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In the Supreme Court of the United States

WYETH LLC, ET AL., PETITIONERS

v.

DONNA SCROGGIN

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether a partial retrial limited to punitive damages violates the Seventh Amendment.

2. Whether a trial court can admit the testimony of a scientific expert without expressly addressing the applicability of the factors set out in *Daubert* v. *Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

PARTIES TO THE PROCEEDING AND CORPORATE DISCLOSURE STATEMENT

Petitioners are Wyeth LLC (formerly known as Wyeth), Wyeth Pharmaceuticals Inc., and Pharmacia & Upjohn Company LLC; respondent is Donna Scroggin. Petitioners are indirect wholly owned subsidiaries of Pfizer Inc. Pfizer has no parent corporation, and no publicly held company owns 10% or more of Pfizer's stock.

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PETITION FOR A WRIT OF CERTIORARI

Wyeth LLC, Wyeth Pharmaceuticals Inc., and Pharmacia & Upjohn Company LLC respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eighth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-44a) is reported at 586 F.3d 547. The district court's opinion granting judgment as a matter of law on punitive damages (App., *infra*, 47a-110a) is reported at 554 F. Supp. 2d 871. The magistrate judge's order admitting expert testimony (App., *infra*, 114a-123a) and the district court's order overruling petitioners' objections to the

magistrate judge's order (App., *infra*, 111a-113a) are unreported.

JURISDICTION

The judgment of the court of appeals was entered on November 2, 2009. A petition for rehearing was denied on December 16, 2009 (App., *infra*, 45a-46a). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

CONSTITUTIONAL PROVISION INVOLVED

The Seventh Amendment to the United States Constitution provides:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.

STATEMENT

Respondent brought suit against petitioners in the United States District Court for the Eastern District of Arkansas, alleging that petitioners had inadequately warned her of the risk of breast cancer associated with their medicines. After a magistrate judge ruled that the testimony of respondent's sole expert on specific causation was admissible, App., *infra*, 119a-120a, and the district court overruled petitioners' objections to that ruling, *id.* at 111a-112a, the case went to trial. A jury found petitioners liable and awarded compensatory and punitive damages. The district court granted judgment as a matter of law to petitioners on punitive damages. *Id.* at 71a-110a. The court of appeals affirmed in part, vacated in part, and remanded for a partial new trial on punitive damages. *Id.* at 1a-44a. As is relevant here, the court of

appeals affirmed the district court's decision to admit the testimony of respondent's expert on specific causation, see *id.* at 27a-31a, and held that a retrial limited to punitive damages did not violate the Seventh Amendment, see *id.* at 43a-44a.

1. Petitioners are Wyeth LLC and Wyeth Pharmaceuticals Inc. (collectively "the Wyeth petitioners") and Pharmacia & Upjohn Company LLC (Upjohn). Petitioners produce prescription medicines colloquially known as "hormone therapy," which have been approved for use for many decades to combat the symptoms of menopause and to prevent osteoporosis. For much of that time, there has been extensive scientific investigation and debate as to whether there is a link between hormone therapy and breast cancer. Since 1988, both the doctor labeling and patient information sheet for the Wyeth petitioners' medicines have warned that "[s]ome studies have suggested a possible increased incidence of breast cancer in those women on estrogen therapy taking higher doses for prolonged periods of time." That warning was approved by the Food and Drug Administration (FDA) and reflected the state of scientific knowledge at the time. App., *infra*, 3a, 5a, 13a, 19a-20a.

In 2002, a study by the Women's Health Initiative (WHI), conducted under the auspices of the National Institutes of Health, reported that women who used hormone therapy were relatively more likely to develop breast cancer than women in the control group, although the absolute rate remained low (*i.e.*, at an annual rate of 38 cases of breast cancer per 10,000 women, rather than 30 cases per 10,000). Based on the results of the WHI study, the Wyeth petitioners revised the breast-cancer warning for their medicines and then made further changes in consultation with the FDA, including placing the warning in a so-called "black box." The FDA to this

day approves petitioners' medicines as safe and effective, and doctors continue to prescribe them. App., *infra*, 17a-21a.

2. In the wake of the WHI study, more than 10,000 women who used hormone therapy and developed breast cancer filed suit against petitioners and other pharmaceutical companies, contending, *inter alia*, that the pharmaceutical companies had inadequately warned of the risk of breast cancer.

Respondent used hormone-therapy medicines produced by petitioners from 1989 to 2000, when she was diagnosed with breast cancer. App., *infra*, 3a. In 2004, respondent brought suit against petitioners in the United States District Court for the Eastern District of Arkansas. As is relevant here, respondent alleged that, notwithstanding the accuracy of petitioners' warnings in light of the state of scientific knowledge at the time, petitioners should have conducted additional testing of the risk of breast cancer from hormone therapy (and that the failure to do so, and to provide different warnings as a result, constituted a failure to warn under Arkansas law).

The Judicial Panel on Multidistrict Litigation established a multidistrict proceeding in the Eastern District of Arkansas, and thousands of similar actions were transferred to that district. After several years of coordinated discovery, the district court began conducting bellwether trials in 2006. The first two trials resulted in defense verdicts; respondent's case was the third to be tried.

As this case comes before the Court, it presents two issues: one concerning the admissibility of the testimony of respondent's principal expert, and the other concerning the permissibility of a retrial limited to punitive damages. With regard to the former issue, respondent

was required to prove at trial that she would not have developed breast cancer but for taking hormone therapy. To that end, respondent relied solely on the testimony of Elizabeth Naftalis, a breast surgeon no longer in active practice, who based her opinion that hormone therapy caused respondent's breast cancer on differential diagnosis—*i.e.*, a method of determining the cause of a patient's illness by considering all of the known causes and individually ruling them out until the most likely causal explanation is left. Citing the factors for the admissibility of expert testimony set out in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), petitioners moved to exclude Dr. Naftalis's testimony on the ground, *inter alia*, that differential diagnosis is an unreliable methodology for determining the cause of an individual's disease where, as is true for breast cancer, the cause is unknown in the vast majority of cases. App., *infra*, 28a.

A magistrate judge denied petitioners' motion and admitted Dr. Naftalis's testimony. App., *infra*, 119a-120a. The magistrate judge acknowledged that Dr. Naftalis's report was "somewhat conclusive, rather than explanatory." *Id.* at 120a. But he stated that he "c[ould] [not] say that Dr. Naftalis used improper methodology." *Ibid.* Citing the district court's ruling admitting the testimony of another expert in an earlier bellwether trial involving a plaintiff with a different medical history, the magistrate judge concluded that Dr. Naftalis was "qualified to testify that [hormone therapy] more likely than not promoted [respondent's] breast cancer," and added that "[h]er conclusions can be tested during cross-examination." *Ibid.* Critically, although the magistrate judge quoted the *Daubert* factors, he did not expressly apply them or even address their applicability. *Id.* at 116a-120a. The district court summarily overruled peti-

tioners' objections to the magistrate judge's order. *Id.* at 111a-112a.

The case then went to trial. The district court bifurcated the trial proceedings; the first phase covered liability and compensatory damages, and the second covered the availability and amount of punitive damages. In the first phase, the jury found petitioners liable and awarded respondent $2.7 million in compensatory damages. In the second phase, the same jury awarded respondent $19.36 million in punitive damages from the Wyeth petitioners and $7.76 million in punitive damages from Upjohn. App., *infra*, 48a.

As is relevant here, petitioners moved for judgment as a matter of law on punitive damages. The district court granted the motion. App., *infra*, 106a-109a. The court determined that it had improperly admitted the testimony of Suzanne Parisian, a doctor whom respondent had designated as her "regulatory expert." *Id.* at 50a, 69a-71a. The court reasoned that Dr. Parisian's testimony merely "tracked [respondent's] legal arguments" and that "there was very little significant analysis." *Id.* at 70a. The court then determined that, absent Dr. Parisian's testimony, there was insufficient evidence to support an award of punitive damages. *Id.* at 71a-73a, 109a.

3. Respondent appealed the district court's decision to grant judgment as a matter of law on punitive damages; petitioners cross-appealed the district court's judgment for respondent on liability on the underlying claim and compensatory damages. The court of appeals affirmed the judgment on liability and compensatory damages; it affirmed the judgment on punitive damages as to Upjohn, but vacated it as to the Wyeth petitioners and remanded for a new trial limited to the availability and amount of punitive damages against those defendants. App., *infra*, 1a-44a.

With regard to the admissibility of Dr. Naftalis's testimony, the court of appeals noted that respondent "suffered from hormone-dependent breast cancer" and that "published research had concluded that hormone-receptor-positive tumors need hormones to grow, that menopausal symptoms result from hormone deficiency, and that there is a link between breast cancer and hormone replacement therapy." App., *infra*, 29a. The court concluded that "Dr. Naftalis sufficiently established that hormones were necessary to the development of [respondent's] tumors and conducted her differential diagnosis from this starting point." *Id.* at 30a. Like the magistrate judge, the court of appeals cited the *Daubert* factors for admissibility of expert testimony, but did not apply them or state why they were inapplicable. *Id.* at 27a-30a.

With regard to punitive damages, the court of appeals held that the district court had correctly excluded Dr. Parisian's testimony but had erred by determining that, absent that testimony, there was insufficient evidence to support an award of punitive damages against the Wyeth petitioners. App., *infra*, 38a-43a. Notwithstanding the absence of any evidence that the Wyeth petitioners had withheld any information regarding the risk of breast cancer or failed to give accurate warnings to respondent and her doctor based on the state of scientific knowledge at the time, the court of appeals determined that, when "[v]iewed as a whole," the evidence "could allow a jury to find or infer that [the Wyeth petitioners] w[ere] guilty of malicious conduct within the meaning of Arkansas law." *Id.* at 42a.

Because "[t]he admission and the jury's consideration of Dr. Parisian's testimony * * * amounted to prejudicial error," the court of appeals held that "the appropriate remedy is a new trial." App., *infra*, 43a. The

court, however, rejected petitioners' contention that a partial retrial limited to punitive damages would be inconsistent with the Seventh Amendment. See Wyeth C.A. Br. 103; Upjohn C.A. Br. 52-53. The court stated, without elaboration, that "a new trial may be had on punitive damages alone without injustice to the parties." App., *infra*, 43a-44a (citing *England* v. *Gulf & Western Mfg. Co.*, 728 F.2d 1026, 1029 (8th Cir. 1984), and *Gasoline Products Co.* v. *Champlin Refining Co.*, 283 U.S. 494, 500 (1931)).

REASONS FOR GRANTING THE PETITION

This case presents two recurring issues of enormous practical significance for civil litigants. In the decision below, the Eighth Circuit held, first, that a partial retrial limited to punitive damages is consistent with the Seventh Amendment, and second, that a trial court can admit the testimony of a scientific expert where the trial court failed to address the applicability of the factors set out in *Daubert*, *supra*. The courts of appeals are in disarray on both issues; the decision below is wrong in both respects; and it is beyond dispute that each issue frequently recurs in modern civil litigation, particularly multidistrict tort litigation of the type at issue here. In cases such as this one, the issues of liability and punitive damages (and the evidence relevant to those issues) will substantially overlap, and a partial retrial limited to punitive damages would thus pose a significant risk of prejudicial confusion. And where a trial court admits expert testimony without expressly considering the *Daubert* factors, there is a very real danger that the resulting ruling will sanction the admission of junk science and sow confusion both on appeal and in other cases involving the same or similar testimony. For those reasons, the Court should grant review and reverse the judgment below.

A. This Court Should Grant Review To Decide Whether A Partial Retrial Limited To Punitive Damages Violates The Seventh Amendment

1. The Courts Of Appeals Are Divided On The Permissibility Of A Partial Retrial Limited To Punitive Damages

a. At English common law, the right to trial by jury was understood as a right to have the same jury hear and decide all of the issues in a case. See *Gasoline Products*, 283 U.S. at 497. Accordingly, "there was no practice of setting aside a verdict in part," and, "[i]f the verdict was erroneous with respect to any issue, a new trial was directed as to all." *Ibid.* As Blackstone explained, an order granting a new trial was understood to "preserve[] [e]ntire * * * that most excellent method of decision"—the jury trial—"which is the glory of the English law." 3 William Blackstone, *Commentaries on the Laws of England* 391 (1768). When a court granted a new trial, therefore, it was "as if [the case] had never been heard before": there was "little prejudice to either party," and neither party could claim an "advantage" from the earlier verdict. *Ibid.*

In relevant part, the Seventh Amendment provides that, "[i]n Suits at common law, * * * the right of trial by jury shall be preserved." As this Court has long recognized, the "right of trial by jury" that the Seventh Amendment "preserve[s]" is "'the right which existed under the English common law when the Amendment was adopted.'" *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 376 (1996) (quoting *Baltimore & Carolina Line, Inc.* v. *Redman*, 295 U.S. 654, 657 (1935)). Although all of the particulars of the right to a jury trial are not "fixed at 1791," *Gasperini* v. *Center for Humanities, Inc.*, 518 U.S. 415, 436 n.20 (1996), the Seventh

Amendment does "preserve the *substance* of the common-law right." *Baltimore & Carolina Line*, 295 U.S. at 657 (emphasis added).

After the Constitution was ratified, some courts began to depart from the common-law practice and permit partial retrials (including in cases governed by state constitutional counterparts to the Seventh Amendment, which does not apply in state-court proceedings, see *Walker* v. *Sauvinet*, 92 U.S. 90, 92-93 (1875)). See, *e.g.*, *Simmons* v. *Fish*, 210 Mass. 563, 565 (1912) (permitting partial retrial of "readily separated" issue). Other courts adhered to the traditional common-law rule and held that a partial retrial, "where the whole case is not submitted in toto to a jury * * *, is not the trial by jury guaranteed by the Seventh Amendment." *McKeon* v. *Central Stamping Co.*, 264 F. 385, 391 (3d Cir. 1920).

b. In *Gasoline Products*, this Court for the first time addressed the constitutionality of partial retrials, in the context of an error involving the calculation of damages on a defendant's breach-of-contract counterclaims. See 283 U.S. at 495-496. The Court determined that the amount of damages on the defendant's counterclaims could not be retried separately from the plaintiff's liability on those counterclaims (although it determined that those issues could be tried separately from the plaintiff's claim for breach of a different contract). *Id.* at 500-501.

The Court acknowledged that all partial retrials were prohibited at common law, but explained that "the form of the ancient rule" was not dispositive because "the Constitution is concerned, not with form, but with substance." *Gasoline Products*, 283 U.S. at 498. The Court instead held, without elaboration, that a partial retrial "may not properly be resorted to unless it clearly appears that the issue to be retried is so distinct and separ-

able from the others that a trial of it alone may be had without injustice." *Id.* at 500.

Applying that standard, the Court concluded that "the question of damages on the counterclaim[s] is so interwoven with that of liability that the former cannot be submitted to the jury independently of the latter without confusion and uncertainty, which would amount to a denial of a fair trial." *Gasoline Products*, 283 U.S. at 500. The Court reasoned that, "upon [a] new trial, the jury cannot fix the amount of damages unless also advised of the terms of the contract," and "the dates of formation and breach may be material, since it will be open to [the plaintiff] to insist upon the duty of [the defendant] to minimize damages." *Id.* at 499.

c. This Court has not addressed the permissible scope of a partial retrial in the nearly eighty years since its decision in *Gasoline Products*. In the meantime, lower courts have struggled to apply *Gasoline Products*' "distinct and separable" standard. Courts have recognized that the *Gasoline Products* standard is "quite difficult to apply in practice" and leads to conflicting results. *Olsen* v. *Carriero*, Civ. No. 92-10961, 1995 WL 62101, at *3 (D. Mass. Feb. 3, 1995) (Saris, J.); see *Hosie* v. *Chicago & N.W. Ry.*, 282 F.2d 639, 642 (7th Cir. 1960), cert. denied, 365 U.S. 814 (1961). One appellate judge criticized the *Gasoline Products* standard on the grounds that "the degree to which facts concerning liability and damages are interrelated seems a quixotic venture with little direct bearing on the justice or injustice of separate trials" and that "it does not lead to any workable standard." *Pryer* v. *C.O. 3 Slavic*, 251 F.3d 448, 461 (3d Cir. 2001) (Mansmann, J., dissenting in part).

In addressing the specific issue whether a partial retrial limited to punitive damages is consistent with the

Seventh Amendment, courts of appeals have generally taken three different approaches.

i. At one end of the spectrum, some courts of appeals have taken a broad view of the Seventh Amendment's protections and concluded that a partial retrial of punitive damages is improper. For example, in *Mason* v. *Texaco, Inc.*, 948 F.2d 1546 (1991), cert. denied, 504 U.S. 910 (1992), the Tenth Circuit upheld a district court's decision on remand to retry the entire case, including both liability and punitive damages. In so doing, the Tenth Circuit explained, in categorical terms, that liability on the underlying claim and punitive damages are interwoven issues:

> A punitive damage claim is not an independent cause of action or issue separate from the balance of a plaintiff's case. It is part and parcel of a liability determination and does not have any independent being until a jury has decided, based on the preponderance of the evidence, that not only was a defendant's conduct negligent, but that it was gross, willful, wanton or malicious. Proof of gross, willful, wanton or malicious conduct by a defendant is not separate from proof of a defendant's negligence. The evidence proving negligence establishes liability and the degree of negligence is determinative in the award of punitive damages. Upon remand in this case, the entire issue of liability was subject to retrial.

948 F.2d at 1554; see, *e.g.*, *Malandris* v. *Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 703 F.2d 1152, 1177-1178 (10th Cir. 1981) (en banc) (holding that, if the plaintiff refused to accept remittitur of a punitive-damages award, "there should be a new trial on all issues since we feel that a new trial on less than all the issues could not be had without confusion and uncertainty, which would

amount to a denial of a fair trial"), cert. denied, 464 U.S. 824 (1983). As recently as last year, the Tenth Circuit reaffirmed its broad view of the Seventh Amendment's protections and refused to remand for a damages-only retrial. See *Haynes Trane Serv. Agency, Inc.* v. *American Standard, Inc.*, 573 F.3d 947, 966-967 (2009).

Similarly, the Third Circuit—which had held before *Gasoline Products* that the Seventh Amendment prohibited partial retrials altogether, see *McKeon*, 264 F. at 390—has long suggested that liability and punitive damages are so inherently intertwined that "the determination of the amount of punitive damages * * * cannot appropriately take place except in connection with the consideration by the jury of the whole question of the defendant's liability and of all the circumstances which it is asserted give rise to that liability." *Smyth Sales, Inc.* v. *Petroleum Heat & Power Co.*, 141 F.2d 41, 45 (1944). More recent Third Circuit decisions are to the same effect. See, *e.g.*, *Simone* v. *Golden Nugget Hotel & Casino*, 844 F.2d 1031, 1040-1041 (1988) (noting that "the issues of liability and damages are interwoven warp and woof on this record" on the ground, *inter alia*, that, "on the question of punitive damages, the jury would have to assess the conduct of the [defendant] to determine whether it acted with malice or in willful disregard of [the plaintiff's] rights"); *Spence* v. *Board of Education*, 806 F.2d 1198, 1202 (1986) (stating that "[t]he liability and damage issues are further intertwined in this case because the plaintiff is seeking punitive damages from the defendants," and explaining that, "[i]n order to prove that the defendants' conduct warranted punitive damages, plain-

tiff would have to present to the jury all the facts leading up to defendants' decision to transfer her").[1]

The Ninth Circuit, while declining to adopt a bright-line rule, has likewise held that "the issues of liability and damages, exemplary or normal, are not so distinct and separable that a separate trial of the damage issues may be had without injustice." *United Air Lines, Inc.* v. *Wiener*, 286 F.2d 302, 306, cert. denied, 366 U.S. 924 (1961). The Ninth Circuit explained that "[t]he question of damages is so interwoven with that of liability that the former cannot be submitted to the jury independently of the latter without confusion and uncertainty which would amount to a denial of a fair trial." 286 F.2d at 306; cf. *Sears* v. *Southern Pac. Co.*, 313 F.2d 498, 503 (9th Cir. 1963) (determining that, "because the evidence [on liability and damages] would largely be the same, a jury should be permitted to consider and apply it, with the aid of the court's instructions, to all issues rather than the isolated one of damages").

ii. At the other end of the spectrum, some courts of appeals have taken a narrow view of the Seventh Amendment's protections and generally permitted partial retrials of punitive damages—often, as in the decision below, with only minimal analysis of the relationship between liability and punitive damages. See, *e.g.*, App., *infra*, 43a-44a; *Grimm* v. *Leinart*, 705 F.2d 179, 183 (6th Cir. 1983) (permitting partial retrial on the ground that "the finding of liability and the award of compensatory damages are in no way intermingled with the improper

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[1] The Third Circuit has suggested that a partial retrial would also be impermissible if the error in the initial trial actually infected other portions of the verdict. See, *e.g.*, *Pryer*, 251 F.3d at 454-455; see generally pp. 15-18, *infra*.

punitive damages instruction"), cert. denied, 465 U.S. 1066 (1984).

In permitting partial retrials of punitive damages (or damages more generally), some courts—most notably, the Seventh Circuit—have recognized "the possibilities for injustice inherent in [partial] new trials." *Watts* v. *Laurent*, 774 F.2d 168, 181 (7th Cir. 1985). Those courts continue to allow partial retrials, but impose conditions on how such retrials should be conducted in an effort to "avoid, or at least minimize, the problems inherent in a procedure" whereby a new jury resolves an issue such as punitive damages without having been present for the initial trial. *Id.* at 181-182. Those conditions include (1) allowing the parties "an opportunity to present to the second jury" any relevant evidence from the initial trial and (2) instructing the second jury that "the relevant issues of liability have been previously decided" and further instructing the jury as to the "legal basis of * * * liability." *Ibid.*; cf. *MCI Communications Corp.* v. *AT&T Co.*, 708 F.2d 1081, 1168 (7th Cir.) (noting, after imposing similar conditions, that "[t]he most difficult part of the decision to remand for a partial new trial on damages is the formulation of rules to guide such a proceeding"), cert. denied, 464 U.S. 891 (1983).[2]

iii. Still other courts of appeals have taken a different approach altogether, focusing not on the extent to

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[2] At least one district court has gone further and concluded that, even where issues of liability and punitive damages are "inextricably intertwined," a partial retrial on damages is nevertheless permissible. *Olsen*, 1995 WL 62101, at *5. Reasoning that a full retrial would "would waste valuable resources (both public and private)," the court held that a partial retrial was permissible as long as "the parties are free to produce all relevant evidence within the framework of a partial trial in damages." *Id.* at *4-*5.

which the issues are interwoven (as *Gasoline Products* requires) but rather on the extent to which the error at the initial trial actually affected other portions of the verdict. For example, the Second Circuit has developed a standard that, in the context of an error affecting damages, considers whether "there is reason to think that the verdict may represent a compromise among jurors with different views on whether defendant was liable or if for some other reason it appears that the error on the damage issue may have affected the determination of liability." *Diamond D Enters. USA, Inc.* v. *Steinsvaag*, 979 F.2d 14, 17 (1992) (internal quotation marks and citation omitted), cert. denied, 508 U.S. 951 (1993); see *Ajax Hardware Mfg. Corp.* v. *Industrial Plants Corp.*, 569 F.2d 181, 185 (2d Cir. 1977) (noting that a partial retrial on damages is proper "only if the district court had been satisfied that the jury properly determined the issue of liability").[3] Under that standard, the Second Circuit has ordered a full retrial in a case involving punitive damages where it could be inferred that "a verdict [was] a compromise" because "damages [were] awarded in an amount inconsistent with the theory of liability offered at trial" and there was "a close question of liability." *Atkins* v. *New York City*, 143 F.3d 100, 104 (1998).

Similarly, the Fifth Circuit has stated that "a court may properly award a partial new trial only when the issue affected by the error could have in no way influenced the verdict on those issues which will not be included in the new trial." *Williams* v. *Slade*, 431 F.2d

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[3] That standard, in turn, appears to have originated in the leading treatise on civil procedure. See 11 Charles Alan Wright, Arthur R. Miller & Mary K. Kane, *Federal Practice and Procedure* § 2814, at 155-156 (2d ed. 1995).

605, 608 (1970). Conversely, where "the decision on the other issues could in any way have been infected by the error," "a new trial must be had on all issues." *Ibid.* Applying that standard, the Fifth Circuit has gone so far as to hold that a defendant who was not liable in the initial trial should be retried together with another defendant in whose favor a directed verdict was improperly granted. *Id.* at 609. And like the Second Circuit, the Fifth Circuit has ordered a full retrial in a case involving punitive damages where it concluded that "the jury's verdict on damages at the first trial suggests some rather fundamental confusion, the source of which is impossible to trace." *Fury Imports, Inc.* v. *Shakespeare Co.*, 554 F.2d 1376, 1388 (1977).

Finally, the Fourth Circuit, while initially focusing on the extent to which the issues are interwoven, see, *e.g.*, *Atlantic Coast Line R.R.* v. *Bennett*, 251 F.2d 934, 938-939 (1958), has more recently gravitated toward the Second Circuit's approach. In one case, the Fourth Circuit, in permitting a partial retrial on punitive damages, rejected the argument that "the district court's decision to set aside the first jury's punitive damage award necessitated a full retrial on all issues because the jury's 'prejudice' may have infected its rulings on [the plaintiff's] substantive claims." *Atlas Food Sys. & Servs.* v. *Crane Nat'l Vendors*, 99 F.3d 587, 599-600 (1996). The court acknowledged that "[a] finding of liability and compensatory damage is not only a prerequisite to finding punitive damages, it provide[s] the jury with important background information." *Id.* at 600. While thus seemingly recognizing that liability and punitive damages were interwoven issues, the Fourth Circuit nevertheless held that a partial retrial on punitive damages was consistent with the Seventh Amendment. This Court should grant review in order to resolve the inconsistency

in the courts of appeals' divergent and irreconcilable approaches.[4]

2. *The Court Of Appeals' Decision To Grant A Partial Retrial Limited To Punitive Damages Is Erroneous*

The court of appeals in this case held that a partial retrial on punitive damages did not violate the Seventh Amendment. App., *infra*, 43a-44a. That holding is incorrect.

a. There can be no serious dispute in this case that the issues of liability and punitive damages are intertwined. In the first phase of the initial trial, the jury was asked to determine whether petitioners failed to warn about the risk of breast cancer associated with their medicines and whether any failure to warn proximately caused respondent's breast cancer; in the second phase, the jury was asked to determine whether, in failing to warn, petitioners acted with malice or in reckless disregard of the consequences. Compare D. Ct. Verdict Form

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[4] The court of appeals' decision in this case is irreconcilable not only with the decisions of other circuits applying *Gasoline Products* in the same or similar circumstances, but also with its own decisions in earlier cases, which had repeatedly "refused to grant a new trial solely on punitive damages" on the ground that "the issue of punitive damages was so interwoven with the substantive merits." *McDonald* v. *Johnson & Johnson*, 722 F.2d 1370, 1388 (8th Cir.), cert. denied, 469 U.S. 870 (1984); see, *e.g.*, *Burke* v. *Deere & Co.*, 6 F.3d 497, 513-514 (8th Cir. 1993), cert. denied, 510 U.S. 1115 (1994); *Slater* v. *KFC Corp.*, 621 F.2d 932, 938 (8th Cir. 1980); *Nodak Oil Co.* v. *Mobil Oil Corp.*, 533 F.2d 401, 411 (8th Cir. 1976). Although such an intracircuit conflict does not independently warrant this Court's review, it further illustrates the disarray in the lower courts concerning the correct application of the *Gasoline Products* standard.

1 (Feb. 25, 2008) with D. Ct. Verdict Form 1 (Mar. 6, 2008).

Given the overlap in the issues, in the second phase of the initial trial, the district court instructed the jury that it "should consider the evidence presented in the first phase of the trial as well as in the second phase." Tr. 2917, 2978. Counsel for respondent similarly invited the jury to consider that evidence in the second phase, Tr. 2646-2649, and both sides repeatedly referred to that evidence in their closing arguments, Tr. 2646-2652, 2661, 2663, 2668, 2670-2671. And for its part, the court of appeals heavily relied on that evidence in concluding that there was sufficient evidence of the requisite state of mind to warrant a new trial on punitive damages for the Wyeth petitioners. See App., *infra*, 4a-22a, 41a-43a.

b. The court of appeals nevertheless summarily held that a partial retrial was consistent with the Seventh Amendment on the ground that "a new trial may be had on punitive damages alone without injustice to the parties." App., *infra*, 43a-44a. Although the court of appeals cited *Gasoline Products*, it made no effort whatsoever to analyze whether the issues of liability and punitive damages are "distinct and separable," as *Gasoline Products* requires. See 283 U.S. at 500. In fact, the overlap between liability and punitive damages in this case is at least as substantial as the overlap between liability and the amount of damages that the Court found to be sufficient to preclude a partial retrial in *Gasoline Products*. See *id.* at 500-501.

In a partial retrial limited to punitive damages, a second jury would necessarily revisit issues related to those decided by the first jury without having the opportunity to see and hear the evidence as it was actually presented to that jury (regardless of whether testimony from the initial trial is read into the record or witnesses

instead testify live for a second time). The second jury would also be deprived of the opportunity to draw all permissible inferences from that evidence, in the event it were instructed to assume that the evidence establishes liability even if the second jury would independently draw the contrary conclusion. Given the overlap in the issues, a partial retrial limited to punitive damages would lead to "confusion and uncertainty" that "would amount to a denial of a fair trial," in contravention of the Seventh Amendment and associated principles of due process. *Gasoline Products*, 283 U.S. at 500.

This Court's decisions defining the constitutional bounds on punitive-damage awards confirm that the issue of punitive damages is not "distinct and separable" from the issue of liability. Since *Gasoline Products*, the Court has explained that the amount of punitive damages must bear a "reasonable relationship" to the amount of compensatory damages. *BMW of North America* v. *Gore*, 517 U.S. 559, 580 (1996). The Court has also made clear that punitive damages may be awarded only for "the conduct that harmed the plaintiff," *State Farm Mut. Auto. Ins. Co.* v. *Campbell*, 538 U.S. 408, 423 (2003), and not for "[the] injury that [the defendant] inflicts upon nonparties," *Philip Morris USA* v. *Williams*, 549 U.S. 346, 353 (2007). In determining whether to award punitive damages, therefore, a jury is required to focus on the defendant's conduct vis-à-vis the plaintiff: specifically, whether, "in committing the wrong complained of, [the defendant] acted recklessly, or willfully and maliciously, with a design to oppress and injure the plaintiff." 1 J.G. Sutherland, *Law of Damages* 720 (1883); see, *e.g.*, *Day* v. *Woodworth*, 54 U.S. (13 How.) 363, 371 (1852). The evidence that is admitted to make that showing, moreover, "must have a nexus to the specific harm suffered by the plaintiff." *State Farm*, 538 U.S. at 422.

As a result, the issue of what is required to award punitive damages not only will, but must as a matter of due process, substantially overlap with the issue of what is required to establish liability on the underlying claim in the first place. The court of appeals' holding that punitive damages can be tried separately from liability threatens to deny petitioners a fair trial, because a jury that is told that the defendant is culpable and that its sole task is to assess the degree of culpability is hardly writing on a clean slate. The Court should grant review in this case to clarify the *Gasoline Products* standard, and hold that a partial retrial limited to punitive damages is inconsistent with the Seventh Amendment.

3. The Permissibility Of A Partial Retrial Limited To Punitive Damages Is An Important And Recurring Issue That Warrants This Court's Review In This Case

The Seventh Amendment issue raised by the court of appeals' decision is an exceptionally important one in modern civil litigation—particularly mass tort litigation of the type at issue here, in which claims for punitive damages have become commonplace. As discussed above, in the nearly eighty years since this Court's decision in *Gasoline Products*, the issue of the permissibility of a partial retrial limited to punitive damages has frequently recurred, often resulting in multiple decisions on the issue in any given court of appeals. See pp. 11-18, *supra*. This case presents an excellent vehicle for consideration of that issue, because the issue was properly preserved and passed upon below. See App., *infra*, 43a-44a; Wyeth C.A. Br. 103, Upjohn C.A. Br. 52-53.

More broadly, a decision by the Court in this case would shed light on the cryptic and confusing *Gasoline Products* standard—and therefore on its application in other contexts in which the issue of the permissibility of

a partial retrial regularly arises. To take but a few examples, lower courts have confronted that issue in cases involving partial retrials on liability, see, *e.g.*, *La Plante* v. *American Honda Motor Co.*, 27 F.3d 731, 738 (1st Cir. 1994); on the amount of compensatory damages, see, *e.g.*, *Broan Mfg. Co.* v. *Associated Distributors, Inc.*, 923 F.2d 1232, 1241 (6th Cir. 1991); on the amount of consequential damages, see, *e.g.*, *Rice* v. *Community Health Ass'n*, 203 F.3d 283, 290 (4th Cir. 2000); on a single claim, see, *e.g.*, *American Home Assurance Co.* v. *Sunshine Supermarket, Inc.*, 753 F.2d 321, 329 (3d Cir. 1985); and for a single defendant, see, *e.g.*, *Bosse* v. *Litton Unit Handling Sys.*, 646 F.2d 689, 694 (1st Cir. 1981). Because of the considerable importance and frequent recurrence of the Seventh Amendment issue both in this specific context and more generally, the Court should grant review on that issue here.

B. This Court Should Grant Review To Decide Whether A Trial Court Can Admit The Testimony Of A Scientific Expert Without Expressly Addressing The Applicability Of The 'Daubert' Factors

1. The Courts Of Appeals Are Divided On The Correct Approach To The Application Of The 'Daubert' Factors

a. The second issue that warrants this Court's review involves the application of the Court's decision in *Daubert*, *supra*. The *Daubert* Court set out four factors relevant to whether the testimony of a scientific expert is sufficiently reliable to be admissible under Federal Rule of Evidence 702. Those now-familiar factors are (1) whether the expert's theory or technique can be and has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether the technique has a known or potential rate of error and standards exist to control its operation; and (4)

whether the theory or technique enjoys general acceptance within a relevant scientific community. See 509 U.S. at 593-594.

In setting out those factors, the Court explained that they do not constitute "a definitive checklist or test." *Daubert*, 509 U.S. at 593. And the Court has since made clear that, in determining how to apply those factors, trial courts have substantial discretion. See *Kumho Tire Co.* v. *Carmichael*, 526 U.S. 137, 153 (1999). At the same time, however, the Court has warned that trial courts "should consider [the *Daubert* factors] where they are reasonable measures of the reliability of expert testimony." *Id.* at 152. In addition, some members of the Court have emphasized that "trial-court discretion in choosing the manner of testing expert reliability * * * is not discretion to abandon the gatekeeping function" or "to perform the function inadequately." *Id.* at 158-159 (Scalia, J., joined by O'Connor and Thomas, JJ., concurring). Instead, "it is discretion to choose among *reasonable* means of excluding expertise that is *fausse* and science that is junky." *Id.* at 159. Thus, while "the *Daubert* factors are not holy writ," "the failure to apply one or another of them [in a particular case] may be unreasonable[] and hence an abuse of discretion." *Ibid.*

b. Since this Court's decision in *Daubert*, the courts of appeals have taken divergent approaches on the extent to which they require trial courts to address the applicability of the *Daubert* factors.

i. On the one hand, some courts of appeals have required specific analysis of the *Daubert* factors and detailed findings of facts. The Fifth Circuit has explicitly provided that, "[i]n the vast majority of cases, the district court first should decide whether the factors mentioned in *Daubert* are appropriate." *Black* v. *Food Lion, Inc.*, 171 F.3d 308, 311-312 (1999). Only then, after "con-

sider[ing] the *Daubert* factors," can the court proceed to "consider whether other factors, not mentioned in *Daubert*, are relevant to the case at hand." *Id.* at 312. In subsequent cases, the Fifth Circuit has repeatedly reaffirmed that approach. See, *e.g.*, *Paz* v. *Brush Engineered Materials, Inc.*, 555 F.3d 383, 388 (2009) (explaining that, "[a]fter the district court considers the *Daubert* factors[,] the [c]ourt then can consider whether other factors . . . are relevant to the case at hand" (internal quotation marks omitted)); *Hathaway* v. *Bazany*, 507 F.3d 312, 318 (2007) (noting that "the district court must decide whether the factors discussed in *Daubert* are appropriate, use them as a starting point, and then ascertain if other factors should be considered").

Similarly, in the Tenth Circuit, a trial court is "required to make specific, on-the-record findings that the testimony is reliable under *Daubert*" before admitting the testimony of a scientific expert. *United States* v. *Roach*, 582 F.3d 1192, 1207 (2009), cert. denied, 130 S. Ct. 1160 (2010). To be sure, the Tenth Circuit has not explicitly required a trial court to decide *first* whether the *Daubert* factors are applicable. But it has stressed that, "[w]hile the district court has discretion in the *manner* in which it conducts its *Daubert* analysis, there is no discretion regarding the actual *performance* of the gatekeeper function." *Goebel* v. *Denver & Rio Grande Western R.R.*, 215 F.3d 1083, 1087 (2000); accord, *e.g.*, *United States* v. *Zhang*, 458 F.3d 1126, 1129 (10th Cir. 2006), cert. denied, 549 U.S. 1187 (2007). Thus, in *Dodge* v. *Cotter Corp.*, 328 F.3d 1212, cert. denied, 540 U.S. 1003 (2003), the Tenth Circuit held that it was an abuse of discretion for the trial court to admit the testimony of a medical expert concerning causation despite the trial court's statements on the record that the expert was well qualified, had reviewed the medical literature, and had

relied on a well-accepted treatise for data. 328 F.3d at 1226. The Tenth Circuit stated that such comments were "insufficient by themselves to fulfill the gatekeeper function." *Id.* at 1227.

The Ninth Circuit has followed the Tenth Circuit's approach. Thus, it has "agree[d] with the Tenth Circuit that 'some * * * reliability determination must be apparent from the record' before we can uphold a district court's decision to admit expert testimony." *Mukhtar* v. *California State University*, 299 F.3d 1053, 1064-1066 (9th Cir. 2002) (quoting *United States* v. *Velarde*, 214 F.3d 1204, 1210 (10th Cir. 2000)). Although the Ninth Circuit also has not explicitly required a trial court to decide as a threshold matter whether the *Daubert* factors are applicable, it does require the trial court to make an explicit finding of reliability. See, *e.g.*, *United States* v. *Jawara*, 474 F.3d 565, 583 (2007); *Hangarter* v. *Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1018 (2004).

ii. On the other hand, some courts of appeals have held that trial courts need not specifically address the applicability of the *Daubert* factors or make detailed findings of fact. The Seventh Circuit has explicitly held that "there is no requirement that the district judge consider each one of [the *Daubert*] 'guideposts' when making an admissibility ruling." *Ancho* v. *Pentek Corp.*, 157 F.3d 512, 515-516 (1998). Other Seventh Circuit decisions are to the same effect. See, *e.g.*, *Walker* v. *Soo Line R.R.*, 208 F.3d 581, 590 (noting, in a case in which "the district court did not articulate explicitly [the expert's] experience in terms of the *Daubert* factors," that "the district court's consideration of the question was not so inadequate as to render it faulty as a matter of law"), cert. denied, 531 U.S. 930 (2000).

The Fourth Circuit has also rejected the proposition that a trial court must specifically analyze the *Daubert* factors in order to comply with *Daubert*'s requirements. See, *e.g.*, *Maryland Casualty Co.* v. *Therm-O-Disc, Inc.*, 137 F.3d 780, 785 (per curiam) (refusing to hold that a trial court must evaluate the *Daubert* factors in considering the admissibility of testimony of scientific expert), cert. denied, 525 U.S. 827 (1998). And the Eleventh Circuit has made clear that, while it "encourage[s] district courts to make specific fact findings concerning their application of Rule 702 and *Daubert* in each case where the question arises," such factfinding is not required. *United States* v. *Lee*, 25 F.3d 997, 999 (1994) (per curiam).

2. The Correct Approach To The Application Of The 'Daubert' Factors Is An Important And Recurring Issue That Warrants This Court's Review In This Case

a. This case constitutes an ideal vehicle for the Court to clarify the correct approach to the application of the *Daubert* factors. It is clear that, if the trial court had addressed the applicability of those factors, it would have determined both that the factors were applicable and that they compelled the exclusion of the expert testimony at issue. That testimony—which was essential to respondent's case—was classic junk science, because it sought to use differential diagnosis to determine the cause of a disease where the cause is unknown in the vast majority of cases.

To begin with, the magistrate judge admitted the testimony of respondent's expert, Dr. Naftalis, without *any* analysis of the *Daubert* factors (or any explanation as to why those factors were inapplicable). See App., *infra*, 119a-120a. Although the magistrate judge cited the district court's ruling admitting the testimony of a different expert in a different trial involving a plaintiff with a dif-

ferent medical history, that ruling likewise did not address the applicability of the *Daubert* factors. See *id.* at 124a-144a. In that ruling, the district court made no finding that using differential diagnosis to determine the cause of breast cancer in an individual woman was a technique that can be or has been tested for accuracy. Rather, the court stated that "reliance on differential [diagnosis] is not fatal when epidemiological studies also support the expert's conclusions," *id.* at 130a—hardly a determination that differential diagnosis was a reliable methodology *in the absence of* those studies. That earlier ruling also did not find that differential diagnosis, as applied to determine the cause of breast cancer in an individual, had been subjected to peer review and publication.[5] And it did not cite any evidence that the use of differential diagnosis to determine the cause of breast can-

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[5] There is no dispute that differential diagnosis is an accepted methodology when the potential causes of a disease are known. But the use of that methodology in other contexts no more proves its reliability here than the general acceptance of diagnosing a fever by use of a thermometer means that using a thermometer is a reliable method for diagnosing breast cancer. When assessing reliability of an expert's method, the issue is not the abstract reasonableness of the method, but rather "the reasonableness of using such an approach * * * to draw a conclusion regarding *the particular matter to which the expert testimony was directly relevant.*" *Kumho Tire*, 526 U.S. at 154. Accordingly, lower courts have frequently concluded that differential diagnosis is inappropriate where, as here, most of the causes of a disease are unknown. See, *e.g.*, *Henricksen* v. *Conoco Phillips Co.*, 605 F. Supp. 2d 1142, 1162 (E.D. Wash. 2009); *Perry* v. *Novartis Pharms. Corp.*, 564 F. Supp. 2d 452, 469 (E.D. Pa. 2008); *Doe* v. *Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 478 (M.D.N.C. 2006).

cer was a generally accepted method within the medical community.[6]

At a hearing before the magistrate judge, moreover, petitioners conclusively demonstrated that the *Daubert* factors supported exclusion of Dr. Naftalis's testimony as unreliable. First, differential diagnosis has never been tested as applied to breast cancer, nor is it easy to conceive of how it could be tested—but, because no doctor has ever used the method outside of the litigation context, the issue has never arisen. Second, differential diagnosis, as applied in this context, has never been peer-reviewed; at the *Daubert* hearing, Dr. Naftalis conceded that she was unable to name any book or article that described the use of differential diagnosis to determine the cause of breast cancer, and she had never presented her theory to her peers nor heard any of her peers present it. See *Daubert* Tr. 1040-1041, 1048-1049. Third, there is no evidence that differential diagnosis has any known or potential rate of error as applied to breast cancer: because scientists do not know what causes most cases of breast cancer and most women who develop breast cancer have not taken hormone therapy, the "conclusion" in litigation of an expert that a specific woman's breast cancer was caused by a specific factor is simply unverifiable. See *id.* at 1023-1024; Resp. C.A. App. 826-827. Fourth, differential diagnosis is not a generally accepted method for determining the cause of breast cancer in either the medical community or by the expert herself in her own practice. See *Daubert* Tr. 1027, 1040-1041, 1048-1049, 1080-1081.

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[6] Notably, the district court subsequently acknowledged that its *Daubert* analysis in the earlier ruling may have been "too lax." Tr. 23 (May 18, 2007).

Because the *Daubert* factors supported exclusion of Dr. Naftalis's testimony, and because respondent failed to offer (and the magistrate judge failed to identify) any plausible reason not to apply those factors in this context, a rule that required a trial court specifically to analyze the applicability of those factors would be outcome-dispositive here. And the practical consequence of the failure to apply the *Daubert* factors was to permit junk science of precisely the type *Daubert* was intended to exclude—scientific testimony relying on a theory that had never been tested, peer-reviewed, applied in practice by the expert, or used outside the context of litigation.[7]

In addition, the magistrate judge's failure to apply (or address the applicability of) the *Daubert* factors rendered his ruling on the admissibility of Dr. Naftalis's testimony virtually impossible to review on appeal. Perhaps not surprisingly, therefore, the district court and the court of appeals similarly failed to analyze and apply the *Daubert* factors. The district court summarily overruled petitioners' objections to the magistrate judge's order. App., *infra*, 111a-112a. And while the court of appeals (like the magistrate judge) cited the *Daubert* factors, it did not apply them or otherwise address petitioners' contention that differential diagnosis was an insufficiently reliable method to determine the cause of respondent's cancer. See *id.* at 27a-30a. At every stage of the judicial

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[7] The linchpin of Dr. Naftalis's theory was that, if a woman has menopausal symptoms, her body necessarily will have insufficient natural hormones to produce breast cancer, enabling Dr. Naftalis to rule out natural hormones as a cause and to identify hormone therapy as the cause instead. If that theory were valid, however, it would necessarily imply that women with menopausal symptoms who did not take hormone therapy were immune from breast cancer—which is contrary to established scientific fact.

process, therefore, the *Daubert* analysis in this case was insufficient. This Court should grant review to clarify that, at least in a case involving the testimony of a scientific expert, a trial court must address the applicability of the *Daubert* factors before discarding those factors and relying on other factors in the reliability analysis.

b. As with the Seventh Amendment issue, the *Daubert* issue is an exceptionally important one to civil litigants. It is no overstatement to say that questions concerning the applicability of the *Daubert* factors arise literally every day in courts around the Nation; in multidistrict litigation, moreover, a single *Daubert* ruling can apply to thousands of cases. Yet this Court has not provided substantial guidance concerning how trial courts should go about the process of applying *Daubert*. In fact, the Court has not addressed *any* aspect of *Daubert* since its decision in *Kumho Tire* more than a decade ago—notwithstanding the central importance of *Daubert* in cases like this one, which as a practical matter will often stand or fall based on the admissibility of expert testimony on issues such as causation. It cannot be disputed that courts around the Nation have radically different views on how they are to perform their vital gatekeeping responsibilities under *Daubert*. This Court should grant review to bring much-needed consistency on an issue of considerable practical significance.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

No. 08-2555, No. 08-2711, No. 08-2713

IN RE: PREMPRO PRODUCTS LIABILITY LITIGATION.

DONNA SCROGGIN, Plaintiff, Appellant,

v.

WYETH, AND ITS DIVISIONS; PHARMACIA & UPJOHN COMPANY, L.L.C., Defendants, Appellees

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May 13, 2009, Submitted
November 2, 2009, Filed

Before WOLLMAN, GIBSON, and MURPHY, Circuit Judges.

WOLLMAN, Circuit Judge.

OPINION

Donna Scroggin was diagnosed with breast cancer eleven years after she began taking estrogen and progestin drugs manufactured by Wyeth Pharmaceuticals Inc. (Wyeth) and Pharmacia & Upjohn

Co. (Upjohn).[1] She sued the companies in 2004 for failure to warn of the risk of breast cancer from combination hormone therapy. The trial was bifurcated, with liability determined first and punitive damages determined second.

A jury returned a verdict finding Wyeth and Upjohn liable and awarding Scroggin compensatory damages. The district court denied Wyeth's and Upjohn's motions for judgment as a matter of law on liability. Following the second phase of the trial, the jury awarded Scroggin punitive damages. Wyeth and Upjohn moved to strike Scroggin's expert witness's testimony and for judgment as a matter of law. The district court granted the motions, vacating the punitive damages award. The district court ruled in the alternative that, had it denied the motions, it would have granted a new trial to determine punitive damages.

Wyeth and Upjohn appeal from the entry of judgment against them on liability, arguing that Scroggin's claim was preempted, that the statute of limitations barred her claim, and that she failed to prove causation. Wyeth and Upjohn also contend that the district court erred in admitting Scroggin's expert evidence on specific causation and in instructing the jury on proximate causation. Scroggin appeals from the district court's order striking her expert evidence during the punitive damages phase of the trial, granting Wyeth's and Upjohn's motions for judgment as a matter of law, and vacating the jury's punitive damages award.

We affirm the jury verdict and its award of compensatory damages. We also affirm the disputed

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[1] This opinion uses the names "Wyeth" and "Upjohn" to refer to the companies, their divisions, and their predecessor companies.

evidentiary orders and jury instruction. We affirm the judgment as a matter of law in favor of Upjohn, but reverse it as to Wyeth, adopting the district court's alternative holding and granting Wyeth a new trial on punitive damages.

I. Factual Background

In 1989, Scroggin began taking combination hormone replacement therapy drugs to relieve menopausal symptoms, including hot flashes and vaginal atrophy. Scroggin was prescribed Ogen, an estrogen product produced by Upjohn, and Provera, a progestin product produced by Upjohn. Dr. Irving Kuperman began treating Scroggin in 1989, and he continued the prescriptions. In 1992, Dr. Kuperman changed Scroggin's estrogen prescription to Premarin, a Wyeth-manufactured drug, and in 1996 he prescribed Prempro, a Wyeth-manufactured drug that combined estrogen and progestin. In 1999, Dr. Kuperman returned Scroggin to the Premarin/Provera combination. When she was diagnosed with ductal carcinoma breast cancer in both breasts in July 2000, her surgeon, Dr. Jim Hagans, discontinued hormone replacement therapy because it is contraindicated for breast cancer.

Scroggin underwent a double mastectomy that removed her breast tissue and the lymph nodes under each arm. After her incisions healed, she underwent six months of chemotherapy, experiencing intermittent nausea, anxiety, fatigue, hot flashes, difficulty sleeping, and continuing memory problems. Chemotherapy was followed by five years of medication to reduce the risk of her breast cancer returning. She remains at risk for recurrence and requires extensive annual examinations

and lab work. Scroggin has chosen not to have reconstructive surgery.

In 2002, the National Institutes of Health (NIH) published the results of its Women's Health Initiative (WHI) study, linking the use of hormone replacement therapy to breast cancer. The WHI study results were widely publicized, and at some point after their publication Scroggin concluded that her breast cancer was the result of her long-term use of estrogen and progestin therapy.

A. Hormone Replacement Therapy

Hormone replacement therapy, consisting of estrogen plus progestin, is prescribed to combat the symptoms of menopause. Women's ovaries typically stop producing estrogen between the ages of forty-five and fifty-five, commencing the onset of menopause. Some women develop moderate to severe symptoms, including intense episodes of heat and sweating, known as hot flashes, as well as vaginal atrophy.

In 1942, Wyeth introduced Premarin, a conjugated equine estrogen intended to replace the estrogen naturally decreasing in women during menopause and reduce the associated symptoms. In 1959, Upjohn launched Provera, a progestin product approved for treatment of abnormal uterine bleeding. By the 1970s, studies showed a link between estrogen replacement drugs such as Premarin and endometrial cancer. It was later determined that prescribing progestin along with estrogen reduced this risk. Although the Food and Drug Administration (FDA) had not approved the combination of estrogen and progestin for treating menopausal symptoms, such combination hormone therapy became the standard of care. Provera was often lawfully

prescribed for this off-label use in conjunction with Premarin. In 1994, Wyeth became the first pharmaceutical company to combine estrogen and progestin into one package with the launch of Prempro. In 1995, Prempro became the first pharmaceutical that combined the two hormones into a single tablet. As of 2008, Premarin and Provera were the most common forms of estrogen and progestin replacement drugs.

B. Wyeth

Premarin is among Wyeth's most profitable products. The company has described Premarin as "our most important asset and our most important priority" and has equated the Premarin marketing efforts with a "Holy War, a Crusade." At trial, Scroggin argued that this devotion led Wyeth to implement a policy of "dismiss and distract" when it came to the risks associated with the drug. Scroggin asserted that Wyeth intentionally ignored the breast cancer risk and avoided its study at the same time as it vigorously promoted Premarin and Prempro. According to Scroggin, Wyeth's "dismiss and distract" policy began in 1975.

1. Wyeth's Reaction to Estrogen Replacement Therapy Being Linked to Endometrial Cancer

In 1975, the FDA's Obstetrics and Gynecology Advisory Committee concluded that there was a link between endometrial cancer and estrogen replacement therapy drugs such as Premarin. The Committee held public hearings, the evidence presented at which suggested a 7.6% increased risk for endometrial cancer among women taking estrogen replacement drugs. This risk decreased to 5.6% for exposure of less than five

years and increased to 13.9% for exposure greater than seven years. Following the hearings, the FDA notified Wyeth that Premarin's label would have to be changed to warn consumers of the risk of endometrial cancer

In response to these hearings and other reports of an endometrial cancer link, Wyeth penned a "Dear Doctor" letter in December 1975. The letter declared that "it would be simplistic indeed to attribute an apparent increase in the diagnosis of endometrial carcinoma, solely to estrogen therapy." The letter went on to state that Wyeth "is vitally concerned about the ultimate resolution of conflicting evidence in this area" and suggested that using the drug as described in the package's labeling would minimize any potential risk and allow for continued use.

Wyeth's letter "in[c]ensed the FDA at all levels, including the Commissioner." Within weeks, FDA officials met with Wyeth executives to discuss the FDA's position that the letter misrepresented the available scientific data. The FDA's Director of Bureau of Drugs stated that he expected Wyeth to provide a sound medical and scientific response to the new information, but instead Wyeth misrepresented scientific findings. Wyeth failed to propose studies to confront the questions that the new data raised and failed to refute or confirm the studies that were then available. The FDA deemed Wyeth's letter a borderline violation of the Food, Drug, and Cosmetic Act and issued a Drug Information Bulletin to "stat[e] objectively the findings linking estrogens in endometrial cancer." Shortly thereafter, the

FDA required a boxed warning[2] of the endometrial cancer risk with every Premarin prescription.

2. Wyeth's Reaction to Hormone Replacement Therapy Being Linked to Breast Cancer

By 1976, the medical community began questioning whether there was a connection between estrogens and breast cancer. In an internal memo dated June 14, 1976, Wyeth doctors recognized that "there is valid concern as to whether or not the use of exogenous estrogen leads to an increase in the incidence of breast cancer," but the memo ultimately concluded that "[e]strogen use does not appear to bring about an increased risk of breast cancer." The following month, Dr. Robert Hoover of the National Cancer Institute at the NIH sent a manuscript of his forthcoming study on menopausal estrogens and breast cancer to Wyeth.[3] Dr. Hoover had concluded that estrogens may be a risk factor for breast cancer, and the study found a 2.0 relative risk[4] for women using estrogen for fifteen years or more. Dr. Hoover's letter stated that

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[2] A boxed warning is defined as "an alert to medical practitioners about potentially serious adverse drug reactions, contraindications, or other special problems with a given drug, contained in a ruled box at a site specified within the label format by the FDA." PDR Medical Dictionary 2145 (3d ed. 2006).

[3] This evidence, along with certain other evidence relied upon in this section, was admitted for a limited purpose. The jury was instructed to consider it solely to determine whether Wyeth was on notice of a duty to test.

[4] Relative risk is the risk of an outcome in one group compared with the risk in another group. The baseline risk is 1.0, meaning that a relative risk of 1.0 or less indicates no greater incidence of the event. A relative risk of 2.0 would indicate a doubling of the baseline risk or a 200% increased risk.

his study's findings were cause for grave concern and that more intensive study was necessary.

Faced with the upcoming publication of Dr. Hoover's study in the New England Journal of Medicine, Wyeth prepared to defend Premarin. Internal correspondence stated that it was crucial to formulate a plan to "mitigate the possible adverse effects" of the study. The correspondence suggested prioritizing the "refutation, or mitigation of the effects" of Dr. Hoover's study, concluding that Wyeth could not "afford to wait for the axe to start its descent before we give serious attention to how we might blunt its edge." Internal documents also showed a concern that the breast cancer risk was being overstated and that the study might affect Premarin's labeling requirements. A Wyeth-sponsored case-control study[6] on mammary cancer was considered, but never materialized. Prescriptions for estrogen in combination with progestin were on the rise, and as a Wyeth document stated, "the number of published, well-designed studies [was] small or practically non existent."

In the late 1980s and early 1990s, additional studies linked hormone replacement therapy to an increased risk of breast cancer. In 1989, Dr. Leif Bergkvist published the results of his long-term study of the risk of breast cancer following estrogen and estrogen-progestin replacement. Although the study had a small sample

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[5] Stedman's Medical Dictionary 1852 (28th ed. 2006) defines case-control study as

> an epidemiologic method that begins by identifying people with the disease or condition of interest (the cases) and compares their past of exposure to identified or suspected risk factors with the past history of similar exposures among those who resemble the cases but do not have the disease or condition of interest (the controls).

size, it nonetheless concluded that treatment with estrogens "seems to be associated with a slightly increased risk of breast cancer, which is not prevented and may even be increased by the addition of progestins." This conclusion was contrary to the prevailing view that progestins might decrease the risk of breast cancer in much the same way that they decreased the risk of endometrial cancer.

In 1990, Wyeth obtained information that Dr. Graham Colditz would present the results of a study showing that Premarin increased the risk of breast cancer by thirty percent in current users. The presentation was scheduled to take place at a meeting of the Society of Epidemiologic Research. Wyeth prepared talking points in advance of the meeting, planning to "effectively position[] the risks vs. benefits so there is some counterbalance to potential negative news." Wyeth implemented a similar plan in response to the International Agency for Research on Cancer's (IARC)[6] announcement that it would evaluate the carcinogenic risks of estrogen replacement therapy. Justin Victoria, Wyeth's Associate Director of Regulatory Affairs, proposed the formation of a task force to "ensure that IARC does not develop a position on a definitive relationship between breast cancer and estrogen replacement therapy as well as to ensure that conjugated estrogens are not singled out from other estrogen replacement therapies as any different in terms of carcinogenic risk."

Throughout the 1990s, Wyeth remained vigilant in disassociating its product from cancer. In accordance

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[6] The IARC is an agency within the World Health Organization charged with identifying cancer-causing agents in the environment.

with company policy, Wyeth denied the Eastern Cooperative Oncology Group's 1993 request for a supply of Premarin to conduct a study of hormone replacement therapy in women who have breast cancer. Presumably, the request was denied because estrogen is contraindicated for breast cancer, but a later memo referred to a custom at Wyeth of denying requests for Premarin for studies involving breast cancer. In 1994, a Wyeth executive responded to the suggestion that a respected oncologist chair an upcoming meeting of Wyeth consultants with "[n]o way having an oncologist chair this. NO NO NO NO & NO." In 1995, a British scientist requested mammograms used in previous Wyeth studies for a study on breast density in estrogen and progestin users. Wyeth agreed on condition that there be "no review of issues currently under discussion in literature elsewhere reviewing HRT and breast cancer" and that the Premarin Study Review Committee "has an absolute and final right to comment on the content, emphasis and conclusions of any publication(s)" and if there are "any significant differences of opinion raised" the scientist "will agree to accept the views of the Premarin Study Review Committee."

In 1996, an NIH-sponsored study, authored by Dr. Steven Cummings, concluded that "the risk of breast cancer associated with hormone replacement therapy may have been substantially underestimated." Wyeth received an advanced abstract of the study and established a breast cancer task force in response. Wyeth's response plan involved the following strategy: "shift attention to other cancers;" characterize the study as "just one more paper;" and highlight flaws in the study's methodology. The task force's stated goal for an upcoming meeting of the American Society of Clinical Oncology was to "[o]vershadow [the] Cummings data" by

directing media attention elsewhere. Handwritten notes regarding the study state "keep US press busy" and "dismiss/distract."

Wyeth also engaged in the lawful, though questionable, practice of commissioning ghost written articles. In 2000, Wyeth tapped Dr. John Eden to author "Breast Cancer and Progestins," but the true author was a technical writing company, hired to produce the manuscript for Wyeth's approval and Dr. Eden's editing. Wyeth submitted a project assignment with references, a timetable, and topics to address, such as "why progestins may not be responsible for the incidence of breast cancer in hormone replacement therapy (HRT) users." The finished product was published in the *Journal of Obstetrics and Gynecology*, apparently without the publication's knowledge of the article's origins and with no reference to Wyeth. Other authors then cited to the article, including Wyeth's own Dr. Ginger Constantine, facilitating its absorption into the collection of reliable medical data.[7]

3. Wyeth's Interactions with the FDA Regarding Hormone Replacement Therapy

Wyeth sought FDA approval of Prempak, a combination product containing Premarin and a progestin tablet, in the 1980s. Wyeth did not support its application with its own study, but instead relied on the then-available studies to substantiate the efficacy and safety of Prempak. The FDA denied the application, concluding that the studies were inadequate and that

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[7] For a recent report regarding the use of ghost-written articles, see Natasha Singer, *Medical Papers By Ghostwriters Pushed Therapy*, N.Y. Times, Aug. 5, 2009, at A1.

Wyeth was unable to assure "the long term safety of the combination treatment for human use."

By the early 1990s, Wyeth was well aware of the FDA's position that the data on estrogen use in combination with progestin was insufficient. In an internal memo dated August 22, 1990, Justin Victoria explained that the FDA had denied Wyeth's applications for combination packaging, informing Wyeth that it could not approve a combination without an adequate, well-controlled clinical trial that evaluated the overall benefits and risks of the combination. The memo stated that the FDA "remain[ed] unconvinced of the overall safety and effectiveness of combined estrogen/progestin therapy." Wyeth and Upjohn also attended the 1990 and 1991 meetings that the FDA held to address, among other issues, the concern that hormone replacement therapy was associated with an increased risk of breast cancer. Both meetings concluded that the current available evidence was insufficient and inconclusive, as some studies showed an increased risk and others did not. Scroggin's regulatory expert and a former Chief Medical Officer with the FDA, Dr. Suzanne Parisian testified at trial that the FDA would have expected Wyeth to take these meetings seriously and that Wyeth should have viewed the 1990 meeting as a red flag. Wyeth, however, considered the meeting a success, celebrating it as a "non-event."

In 1991, Wyeth sought FDA approval of its Premarin marketing plan and the plan's centerpiece, a magazine. In a February 21, 1991, letter to Wyeth, the FDA's Acting Director of the Division of Drug Advertising and Labeling stated that the FDA "view[ed] this campaign in its entirety to be a form of extremely insidious hidden persuasion" and a "marketing ploy masquerading as

concern for the health of postmenopausal women." The letter described the magazine as a "house organ," faulting it as misleading for failing to clearly state Wyeth's sponsorship and for stating that the magazine was provided by a pharmacy. Moreover, the letter criticized the magazine's articles as misleading. The letter remarked that the campaign "*intentionally* misleads the reader into thinking that her physician is somehow responsible for providing it to her." Wyeth subsequently altered the campaign.

In 1994, the FDA approved Prempro, a combination packaging of estrogen and progestin, on the condition that Wyeth perform a post-marketing study on the risk of breast cancer. Dr. Parisian testified that the FDA cannot force a pharmaceutical company to perform safety tests and suggested that approval was granted as a means of compelling the study. Such a study would take eight or nine years to complete.

Following the FDA's approval of Prempro, Wyeth requested that its support of the following two studies satisfy its obligation to study the breast cancer risk: the WHI study and the Women's International Study of Long-Duration Oestrogen After Menopause. The WHI study was underway and was evaluating whether combination use of estrogen and progestin provided long-touted cardiovascular benefits. Although the FDA had previously expressed skepticism that the WHI study could evaluate the breast cancer risk, it approved Wyeth's proposal.

C. Upjohn

Evidence presented at trial did not show that Upjohn tried to undermine evidence linking breast cancer to hormone replacement therapy or its progestin, Provera.

Instead, Scroggin argued that Upjohn failed to study whether hormone replacement therapy increased the risk of breast cancer and that it ignored the growing evidence indicating that such a risk existed.

1. Upjohn's Reaction to Hormone Replacement Therapy Being Linked to Breast Cancer

As early as 1963, Upjohn was aware that Provera might exacerbate existing breast cancer.[8] In 1970, Upjohn withdrew Provest, an oral contraceptive containing estrogen and progestin, after a study showed that progestin caused mammary nodules in beagle dogs. Recognizing that Provest's withdrawal might alarm doctors prescribing combination hormone therapy drugs, Upjohn issued a "Dear Doctor" letter that assured that there was "no reason to predict human extrapolation of this finding," but that there was also no way of disproving it. The letter distinguished Provest, a contraceptive used for a prolonged period of time for which there were adequate replacements, from Provera, a "therapeutic agent[] for specific gynecological disorders." The letter concluded that Provera's benefits outweighed the possible risks and that continued use "poses no unwise risk in this regard to you or your patients."

In 1990, Upjohn hired the Degge Group to gather and review all available scientific data concerning the risk of breast cancer with hormone replacement therapy involving progestin. The goal was to determine what was known and what areas needed further research. The

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[8] Scroggin established at trial that Upjohn would have been aware of the same medical literature and research as Wyeth.

Degge Group found that the evidence was inconclusive, and it identified and recommended areas for further research. The Degge Group published the results of its research in 1992, in Fertility and Sterility, an obstetrics and gynecology medical journal. Upjohn, however, did not conduct follow up studies or research.

By 1992, Upjohn still did not know the extent of the risk of breast cancer with progestin use as part of hormone replacement therapy. Between 1982 and 1994, Upjohn conducted thirty-four studies to prove that Provera protected the endometrium. The studies were monitored for breast cancer, but they were not designed to be large enough or long enough in duration to be capable of evaluating the breast cancer risk.

Until 1995, there remained a prevailing view that progestin's addition to estrogen replacement therapy might reduce the incidence of breast cancer in much the same way that it reduced the risk of endometrial cancer. In 1995, however, a publication by Dr. Colditz examined available data from 1978 through 1992 and concluded that there was no benefit. In fact, the study found a slightly higher risk with the addition of progestin. Dr. Colditz "observed a significant elevation in the risk of breast cancer among women using conjugated estrogen alone," a relative risk of 1.32; for estrogen and progestin, the relative risk was 1.41; and for progestin alone, the relative risk was 2.24.

2. Upjohn's Interactions with the FDA Regarding Hormone Replacement Therapy

In 1966, Upjohn applied for FDA approval of Provera's use with estrogens for treatment of menopause. The FDA denied the application because Upjohn failed to justify the requested indication with

adequate clinical data. In 1986, Upjohn submitted a supplemental application to the FDA, again seeking to expand Provera's indications for use of the drug to oppose the endometrial effects of estrogen in menopausal women receiving estrogen replacement therapy. The FDA denied the application because Upjohn failed "to provide substantial evidence consisting of adequate and well-controlled studies . . . that Provera will have the effect it is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling."

Although Provera was not approved for use in treating menopausal symptoms, Upjohn advertised it as such. In 1984, the FDA called for the immediate cancellation of Provera advertisements appearing in Contemporary OBGYN. The advertisements promoted Provera's off-label use with estrogen replacement therapy and failed to mention its indicated use, treatment for abnormal uterine bleeding. Upjohn agreed to limit its advertisements to the approved indication. Notwithstanding that agreement, the FDA found it necessary to request immediate cancellation of a similar advertisement in 1985, and another advertisement in 1990, that claimed Provera was "the *other* half of hormone replacement therapy." In 1991, Upjohn submitted proposed promotional materials to the FDA for approval. The FDA limited the material because it was potentially misleading. The FDA reminded Upjohn of their previous discussions "regarding material which suggests that Provera is indicated for use in postmenopausal replacement therapy for the prevention of endometrial hyperplasia."

In 1998, Provera was finally approved "for the reduction of endometrial hyperplasia in postmenopausal

women" who are receiving estrogen. Testimony at trial revealed that Upjohn did not conduct any breast cancer studies from 1960 until the time of trial.

D. The Women's Health Initiative Study

The WHI study began in 1991. The study consisted of multiple components, one of which was an evaluation of the use of estrogen and progestin in postmenopausal women. Primarily, this component evaluated whether estrogen and progestin use decreased the incidence of cardiovascular disease. Secondarily, the study assessed numerous safety issues, including the risk of breast cancer. The study was organized as a randomized placebo-controlled trial, meaning that one group of women received the drugs and the other a placebo. The average age of the participants was sixty-three, and it included women who were already on hormone replacement therapy, as well as women who began treatment at the start of the study. The study had a predetermined stopping point if the incidence of breast cancer exceeded a certain point. In 2002, three years short of its scheduled completion, the NIH terminated the study, finding an unacceptably high incidence of invasive breast cancer among the participants.

In July 2002, the initial results of the WHI study were published in the Journal of the American Medical Association. The study reported a relative risk of breast cancer of 1.24 over 5.6 years of estrogen and progestin use. Stated differently, the estrogen plus progestin group was twenty-four percent more likely to develop breast cancer than the control group. This result was consistent with estimates from pooled epidemiological data. Wyeth's Dr. Constantine described the relative risk of increased incidence of breast cancer as small and

Scroggin's medical expert, Dr. Don Austin, described it as slightly elevated. The study also found that the risk of breast cancer decreased after stopping the hormone therapy.

These initial results, however, contained variables not accounted for in the 1.24 relative risk. Dr. Austin testified that the 1.24 number was misleading, particularly for women using hormone replacement therapy for long periods of time. He noted that although randomized clinical trials assist in showing causal relationships, they may not be accurate in reporting the size of the risk. The 1.24 relative risk was based on the "intent to treat" group, meaning the women who had signed up to participate in the study, but it did not account for those who had dropped out during the course of the study. According to the WHI, all of the women had been enrolled for 3.5 years, with an average enrollment of 5.2 years, and a maximum enrollment of 8.5 years. Forty-two percent of estrogen plus progestin users and thirty-eight percent of the placebo group ceased participating during the course of the study. The initial WHI results, however, calculated the relative risk as if these women had remained in the study.

In 2006, Dr. Garnet Anderson, who had worked on the WHI study, published a report that accounted for these variables. When she accounted for confounding variables, the relative risk was 1.96. She found that women who had been taking hormone replacement therapy prior to commencement of the study had a relative risk of 2.78 and that women who were taking the medication for more than five years had a relative risk of 2.5. When Dr. Anderson analyzed only the women who remained in the study and adhered to the treatment, she found a relative risk of 3.56.

Dr. Austin testified that "the true value is somewhere between 1.18 and 10.73, but the best estimate is 3.56." Dr. Colditz asserted that the relative risk is somewhere between 2.0 and 4.0 depending on use and duration. Both Dr. Colditz and Dr. Austin agreed that estrogen plus progestin use causes breast cancer. Additionally, the IARC has classified estrogen plus progestin as a carcinogen of the breast.

E. Wyeth's and Upjohn's Breast Cancer Warnings

The FDA requires drug information to be sent directly to the physician as well as provided to the patient with each prescription. In 1992, both the physician labeling and patient information sheet for Premarin provided the following warning: "Some studies have suggested a possible increased incidence of breast cancer in those women on estrogen therapy taking higher doses for prolonged periods of time. The majority of studies, however, have not shown an association with the usual doses used for estrogen replacement therapy." Similar language was included in the physician label and patient information sheet accompanying Prempro prescriptions.[9] The Premarin labeling did not provide any information concerning the combined use of estrogen plus progestin. Both Dr. Parisian and Dr. Kuperman testified that this label did not convey a significant risk of breast cancer associated with the use of estrogen or progestin.

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[9] The Prempro label had the following modification: "Some studies have reported a moderately increased risk of breast cancer (relative risk 1.3 to 2.0) in those women on estrogen replacement therapy taking higher doses, or in those taking lower doses for prolonged periods of time, especially in excess of 10 years."

The Prempro information sheet included this additional information:

> Most studies have not shown a higher risk of breast cancer in women who have ever used estrogens. However, some studies have reported that breast cancer developed more often (up to twice the usual rate) in women who used estrogens for long periods of time (especially more than 10 years), or who used high doses for shorter time periods. The effects of added progestin on the risk of breast cancer are unknown. Some studies have reported a somewhat increased risk, even higher than the possible risk associated with estrogens alone. Others have not. Regular breast examinations by a health professional and monthly self-examination are recommended for all women. Regular mammograms are recommended for all women over 50 years of age.

Dr. Parisian testified that the Prempro warning was confusing and did not clearly convey a risk to patients. She also testified that it falsely implied that Wyeth had conducted studies to analyze the risk. Dr. Kuperman testified that the warning provided no clear indication of a breast cancer risk and instead implied that the risk was unresolved and that there was likely a low correlation.

In 1999, the Prempro label continued to provide the warning contained in the Premarin label, but added, "[t]he effect of added progestins on the risk of breast cancer is unknown, although a moderately increased risk in those taking combination estrogen/progestin therapy has been reported." The label provided an example of a clinical trial and concluded that "[t]he overall incidence of breast cancer in this clinical trial does not exceed that expected in the general population."

Upjohn's Provera provided no warning of breast cancer, and none was required by the FDA until 1999. At that time, the label informed patients of the results of the study on beagle dogs and concluded that the "significance with respect to humans has not been established."

F. Current Status of Hormone Replacement Therapy

Premarin, Provera, and Prempro continue to be prescribed today, and the FDA still considers the drugs safe and effective. The FDA now requires, however, the drugs' labels to reflect the results of the WHI study, and all three medications now contain a boxed warning of the risk of breast cancer. Following the release of the WHI results, the number of prescriptions dropped significantly. This drop in prescriptions was accompanied by a corresponding reduction in the number of cases of breast cancer diagnosed in the United States. Likewise, a retrospective review has since shown that breast cancer increased as prescriptions for hormone replacement therapy increased.

Dr. Kuperman's prescription habits have also changed. Although he testified that he has always warned of the known risks and prescribed the lowest effective dose, he now relies on the WHI study and subsequent studies to provide a more accurate assessment of the risks to his patients. As a result of the study, Dr. Kuperman aims to keep the duration of estrogen plus progestin use to less than five years, and he no longer prescribes hormone replacement therapy for durations of ten or fifteen years. Instead, he tries to wean patients off hormone replacement therapy. Following the study results, Dr. Kuperman told Wyeth

sales representatives who had routinely visited his office that he had a negative opinion of Prempro and no longer wanted samples. Since 2002, his prescriptions for estrogen plus progestin have decreased.

G. Procedural Background

After a nearly three-week-long trial, the jury found that Wyeth and Upjohn had inadequately warned about a known or knowable risk of breast cancer from ingestion of Premarin, Provera, and Prempro and that this failure to warn was the proximate cause of Scroggin's breast cancer. The jury awarded Scroggin compensatory damages in the amount of $2.7 million. Following a three-day trial, the jury found Wyeth liable for $19.36 million and Upjohn liable for $7.76 million in punitive damages. The district court granted Wyeth's and Upjohn's motions for judgment as a matter of law as to punitive damages, finding that much of Dr. Parisian's punitive damages testimony should not have been admitted and that the remaining evidence did not support the verdict.

II. Analysis

Wyeth and Upjohn raise a number of issues regarding the liability phase of the trial, which we examine in turn. Scroggin appeals the district court's post-judgment order striking her expert's testimony and related exhibits on punitive damages phase and granting Wyeth's and Upjohn's motion for judgment as a matter of law on punitive damages.

A. Preemption

Wyeth and Upjohn contend that Scroggin's state law claim for failure to warn is preempted by federal law.

Because the FDA regulates pharmaceutical products and oversees labeling requirements, they argue that there can be no heightened duty under Arkansas law and that they could not comply with state law without violating FDA requirements.

The Supreme Court's recent decision in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), has foreclosed this preemption argument. In *Levine*, a Vermont jury found that Wyeth had inadequately warned about the risk of irreversible gangrene arising from the intravenous push administration of its drug, Phenergan. *Id.* at 1193. The Court rejected Wyeth's preemption arguments, noting that federal regulations do not prohibit drug manufacturers from strengthening their warnings prior to FDA approval to reflect new developments and comply with state laws. *Id.* at 1196-97.

> [I]t has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.

Id. at 1197-98. As in *Levine*, there is no evidence that the FDA would not have permitted the strengthening of the labels of Premarin, Prempro, and Provera in a manner consistent with Arkansas law.

Likewise, Wyeth and Upjohn have not shown that state requirements obstruct the purposes of federal drug labeling regulation. Given the limited resources of the FDA and the extensive assortment of pharmaceutical products on the market, "the FDA [has] traditionally regarded state law as a complementary form of drug regulation." *Id.* at 1202. Congress is aware of the

potential for conflict and has enacted an express preemption provision for medical devices, but there is no such enactment for prescription drugs, *id.* at 1200, and none will be implied.

B. Statute of Limitations

Wyeth and Upjohn appeal from the district court's denial of their motion for judgment as a matter of law on their statute of limitations defense, arguing that Scroggin was aware of the risk of breast cancer while taking hormone replacement therapy and that her claim thus began to accrue when she was diagnosed with breast cancer. We review *de novo* a district court's determination on a motion for judgment as a matter of law. *Carter v. Kan. City S. Ry. Co.*, 456 F.3d 841, 846 (8th Cir. 2006). "We apply the same standards as the district court, giving the nonmoving party all reasonable inferences and viewing the facts in the light most favorable to the nonmoving party. If conflicting inferences reasonably can be drawn from evidence, the jury is in the best position to determine which inference is correct." *Christensen v. Titan Distrib., Inc.*, 481 F.3d 1085, 1092 (8th Cir. 2007) (citations and internal quotations omitted).

Arkansas law provides a three year statute of limitations on product liability actions. Ark. Code Ann. § 16-116-103.

> A cause of action accrues when the plaintiff first becomes aware of her condition, including both the fact of the injury and the probable causal connection between the injury and the product's use, or when the plaintiff by the exercise of reasonable diligence, should have discovered the causal connection between the product and the injuries suffered.

Uhiren v. Bristol-Myers Squibb Co., 346 F.3d 824, 828 (8th Cir. 2003) (relying on Arkansas law) (citations and internal quotations omitted). Scroggin contends that discovery of a probable causal connection was not possible until the WHI findings were released.

Wyeth and Upjohn argue that the WHI findings revealed nothing significant to Scroggin; therefore, whatever Scroggin knew in 2002, she knew in 2000 when she was diagnosed with breast cancer. We conclude that a jury could find that Scroggin's cause of action accrued at some point after the publication of the WHI study's results. Wyeth and Upjohn changed their products' labeling significantly following the publication of the WHI findings, devoting substantial label space to the results of the study. Moreover, the WHI results were widely covered in mainstream media,[10] and Prempro sales have dropped by fifty percent since 2001, suggesting that the WHI study did more than affirm that which was already known.

Wyeth and Upjohn also contend that Scroggin should have known of the breast cancer risk because she received the product warnings, she read the warnings, and Dr. Kuperman discussed these warnings with her. Two doctors testified that the labels Scroggin would have read did not convey a significant risk of breast cancer, and Dr. Kuperman thought the labels indicated that the evidence was inconclusive. Thus, Scroggin

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[10] The WHI study was the subject of Time Magazine's July 22, 2002 cover story, "The Truth About Hormones: A large, federally funded study provides definitive proof that estrogen and progestin are not age-defying wonder drugs. What's a woman to do?" The New York Times recently reported that the "[u]se of treatment plunged after [the WHI] findings were reported." *Study Cites Hormones As Cancer Risk*, N.Y. Times, July 15, 2009, at A13.

presented sufficient evidence for the jury to find that the warnings were inadequate, contradictory, and confusing.

Wyeth and Upjohn also assume knowledge on Scroggin's part because Dr. Hagans instructed her to stop taking hormone replacement therapy when he diagnosed her with breast cancer. This argument fails, for the Premarin and Prempro labels stated that women already known to have breast cancer should not use Premarin or Prempro. The label included that instruction because estrogen is contraindicated for women with breast cancer, meaning that it can exacerbate their existing breast cancer and, as Justin Victoria testified, not because it suggests a causal connection. *Cf. Roth v. G.D. Searle & Co.*, 27 F.3d 1303, 1308 (8th Cir. 1994) (noting that the doctor's statement that the plaintiff never should have had the second intrauterine device inserted, coupled with unchallenged, plainly stated product warnings, put the plaintiff on inquiry notice).

The assertion that Scroggin would have been aware of the risk through her own due diligence is also without merit, for it ascribes to Scroggin the duty of being aware of not simply the possibility that her hormone replacement therapy caused her breast cancer, but that a causal connection was probable. The jury could reasonably conclude that if medical doctors were unsure of the risk, it is highly unlikely that a layperson would be more aware of that risk. *See Deutsch v. Wyeth, Inc.*, No. MID-L-998-06 MT (N.J. Super. Ct. June 14, 2007) (order denying Wyeth's motion for summary judgment based on statute of limitations) ("It is . . . entirely unreasonable to require a patient without medical training to make the logical connection between her ingestion of HRT drugs and her breast cancer and possess a reasonable belief

that she could sue Wyeth for her injuries before the WHI findings were released to the public.").

C. Causation

Wyeth and Upjohn assert that Scroggin failed to prove that their drugs were the cause of her injury. As part of her failure to warn claim, Scroggin was required to show both specific causation—that the hormone replacement therapy caused her injury—and proximate causation—that she would not have taken the combination therapy had Wyeth and Upjohn provided adequate warnings. *See Ashley County v. Pfizer, Inc.*, 552 F.3d 659, 667 (8th Cir. 2009). Wyeth and Upjohn argue that the district court erred in admitting the testimony of Scroggin's specific causation expert, in instructing the jury on proximate cause, and in denying their motion for judgment as a matter of law because the evidence showed that Scroggin would not have done anything differently if an adequate warning had been provided.

1. Admission of Dr. Naftalis's Expert Testimony

Wyeth and Upjohn argue that the district court erred in admitting the testimony of Dr. Elizabeth Naftalis, Scroggin's expert witness on specific causation. "[A]bsent a clear and prejudicial abuse of discretion," we will not reverse a district court's determination on the admissibility of expert testimony. *Bland v. Verizon Wireless, L.L.C.*, 538 F.3d 893, 896 (8th Cir. 2008).

Federal Rule of Evidence 702 provides for the admission of an expert opinion if it "will assist the trier of fact to understand the evidence or to determine a fact in issue," provided the expert is qualified to render the

opinion and offers sufficient factual basis for her opinion, forms her opinion on reliable principles and methods, and applies these principles or methods to the facts of the case. Rule 702 reflects a "relax[ation of] the traditional barriers to opinion testimony," and the court's inquiry is intended to be flexible. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 588, 594, (1993) (internal quotations omitted). The district court must assess whether the methodology used by the proposed expert is valid and whether it was properly applied.[11] *Id.* at 592-93. "There is no single requirement for admissibility as long as the proffer indicates that the expert evidence is reliable and relevant." *Unrein v. Timesavers, Inc.*, 394 F.3d 1008, 1011 (8th Cir. 2005).

Wyeth and Upjohn did not challenge Dr. Naftalis's qualifications as an expert witness before the district court, and they do not argue that the method she used, differential diagnosis, is not a sound and accepted methodology. Instead, they argue that differential diagnosis cannot be used to prove the cause of breast cancer because no one knows the cause of breast cancer. They note that Dr. Naftalis was not familiar with the details of Scroggin's family history of breast cancer until trial, and they argue that she did not properly account for Scroggin's various risk factors for breast cancer, such as breast density, her age, weight, and her smoking history.

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[11] *Daubert* sets forth the following four factors for consideration, which do not constitute a definitive checklist or test: (1) whether the theory or technique applied can be tested, (2) whether the theory or technique has been subject to peer review or publication, (3) the known or potential rate of error, and (4) general acceptance. *Daubert*, 509 U.S. at 593-95.

Scroggin suffered from hormone-dependent breast cancer. Dr. Mariann Harrington, Scroggin's oncologist, tested the tumors in Scroggin's breasts for hormone receptors to inform her treatment. Both the left and right tumors were one hundred percent positive for estrogen and progesterone receptors. There was no dispute at trial that hormone-receptor-positive tumors are dependent upon hormones for their growth. Moreover, published research had concluded that hormone-receptor-positive tumors need hormones to grow, that menopausal symptoms result from hormone deficiency, and that there is a link between breast cancer and hormone replacement therapy. *See Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 693 (8th Cir. 2001) (noting that "scientific reliability can also be shown by proof that the research and analysis supporting the proffered conclusions have been subjected to normal scientific scrutiny through peer review and publication").

Knowing that Scroggin's breast cancer was hormone dependent, Dr. Naftalis's differential diagnosis sought to determine the cause of Scroggin's breast cancer by ruling out the two possible sources of these hormones: (1) Scroggin produced the hormones herself, or (2) they came from the hormone replacement therapy she had taken for the past eleven years. Scroggin presented evidence that her menopausal symptoms were relieved by hormone replacement therapy, confirming that her own body was unable to produce sufficient hormones and therefore could not be the cause.[12] The remaining source

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[12] Although Wyeth presented evidence disputing this association, the factual basis of an expert opinion is assessed by the jury, *Larson v. Kempker*, 414 F.3d 936, 941 (8th Cir. 2005), and the jury may have been persuaded by Wyeth's own documents asserting a link between hormone deficiency and uncomfortable menopausal symptoms.

was the combination of Premarin, Provera, and Prempro. Accordingly, Scroggin presented evidence establishing a causal link between breast cancer and estrogen plus progestin use, particularly for the length of time Scroggin was taking the drugs.

We find unpersuasive the contention that Dr. Naftalis's testimony should not have been admitted because Scroggin has some breast cancer risk factors and a family history of breast cancer. Dr. Naftalis sufficiently established that hormones were necessary to the development of Scroggin's tumors and conducted her differential diagnosis from this starting point. Although not necessary to the formation of her opinion, Dr. Naftalis addressed the known causes of breast cancer and possible risk factors. Wyeth and Upjohn argue that this review was insufficient, but Dr. Naftalis's "explanations as to conclusions not ruled out went to weight and not admissibility." *Id.* at 694. Additionally, Scroggin submitted to every available genetic test for breast cancer, all of which came back negative for the most common breast cancer genes. Wyeth's genetics expert testified that he continues to believe that genetics caused Scroggin's breast cancer, but the jury concluded otherwise.

Wyeth's and Upjohn's reliance on *Bland v. Verizon Wireless, L.L.C.* is misplaced. 538 F.3d 893 (8th Cir. 2008). In that case, expert testimony was offered to show that the plaintiff's recent exposure to freon caused her exercise-induced asthma. *Id.* at 897. The exact cause of exercise-induced asthma is not known, and the plaintiff's expert could not provide a reliable opinion as to what

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Further, Wyeth has not disputed that vaginal atrophy is caused by estrogen deficiency.

caused the plaintiff's asthma. *Id.* at 898. The proximity in time between the plaintiff's exposure to freon and her resulting asthma was the only basis for her doctor's opinion; the doctor failed to investigate other possible causes, including Bland's home or other environments. *Id.* Conversely, Dr. Naftalis was able to testify that Scroggin's breast cancer would not have developed without hormone replacement therapy because Scroggin's body was not producing sufficient amounts of hormones to allow hormone-receptor-positive tumors to develop. Thus, Dr. Naftalis ruled out the other possible cause of Scroggin's breast cancer, and her expert testimony was properly admitted.[13] Wyeth and Upjohn had the opportunity to expose the testimony's weaknesses through vigorous cross-examination and the presentation of contrary evidence. *See Daubert*, 509 U.S. at 596.

2. Jury Instruction on Aggravation of Preexisting Condition and Promotion

Wyeth and Upjohn argue that the district court erred in modifying the Arkansas Model Instruction on proximate cause to reflect Scroggin's theory that estrogen plus progestin use promotes preexisting

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[13] The Minnesota Court of Appeals's recent unpublished opinion, *Zandi v. Wyeth, Inc.*, No. 27-CV-06-6744, 2009 WL 2151141 (Minn. Ct. App. July 21, 2009) (unpublished), is distinguishable. Although *Zandi* involves similar facts, Minnesota law requires a more conservative review of expert testimony than the liberal thrust of the Federal Rules of Evidence and relies on a variant of the standard abandoned in *Daubert*. To the extent that *Zandi* excludes an expert opinion that relies on differential diagnosis to determine the cause of hormone-receptor-positive breast cancer in an individual with hormone-dependent breast cancer, we respectfully disagree.

abnormal cells into malignancies. "We review a district court's decision on jury instructions for abuse of discretion, looking to the instructions as a whole to determine whether they fairly submitted the issues to the jury." *Boerner v. Brown & Williamson Tobacco Co.*, 394 F.3d 594, 603 (8th Cir. 2005). "We afford the district court broad discretion in choosing the form and language of the instructions and will reverse a jury verdict only if the erroneous instruction affected a party's substantial rights." *In re Prempro Prods. Liab. Litig.*, 514 F.3d 825, 829 (8th Cir. 2008) (internal quotations omitted) (quoting *Slidell, Inc. v. Millennium Inorganic Chems., Inc.*, 460 F.3d 1047, 1054 (8th Cir. 2006)).

"Model jury instructions are just that, models. They are not mandatory." *United States v. Wilson*, 565 F.3d 1059, 1067 (8th Cir. 2009). The district court was not required to precisely follow Arkansas's Model Instruction, but only to "fully and properly instruct upon all the elements of the case in light of controlling Arkansas law." *Wright v. Farmers Co-op of Ark. & Okla.*, 620 F.2d 694, 698 (8th Cir. 1980) (internal quotations omitted) (citing *Stafford v. S. Farm Bureau Cas. Ins. Co.*, 457 F.2d 366, 367 (8th Cir. 1972) (per curiam)).

Under Arkansas law, "proximate cause is that cause which, in a natural and continuous sequence, produces damage." *Sluder v. Steak & Ale of Little Rock, Inc.*, 206 S.W.3d 213, 218 (Ark. 2005) (internal quotations omitted) (citing AMI Civ. 3d 501; *Bull v. Manning*, 433 S.W.2d 145 (Ark. 1968); *Ben M. Hogan & Co. v. Krug*, 351 S.W.2d 451 (Ark. 1961)). The district court's instruction included this precise language, as well as the following definitions:

> A 'producing' cause is one that in natural and continuous sequence causes or initiates injury and without which the injury would not have occurred. A 'promoting' cause is one that in natural and continuous sequence aggravates a pre-existing condition or disease and without which the full extent of the injury would not have occurred.

The court then clarified that the jury was to view the evidence in light of these definitions rather than how they may have been used during the trial.

Wyeth's argument[14] acknowledges only two possible theories of Scroggin's case: either Scroggin already had breast cancer and the hormone replacement therapy aggravated it, or the therapy initiated the transformation of normal cells into cancerous cells. Given these alternatives, Wyeth asserts that including "promoting" in the instruction unfairly elevated Scroggin's presentation of the evidence and that the instruction was not supported by the evidence. Wyeth has refused to recognize Scroggin's theory of causation. Scroggin presented evidence that she had abnormal or susceptible cells, which were a pre-existing condition. In other words, she had these cells prior to her regimen of estrogen plus progestin. She also presented evidence that estrogen and progestin caused these cells to become cancerous. Dr. Colditz has described estrogen plus progestin's effect on these abnormal cells as "acting like a fertilizer to get them to grow rapidly and progress on to cancer." Dr. Naftalis testified that combination hormone therapy has a "promotion effect" on the "susceptible cell and turns it into cancer." Dr. Colditz

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[14] Upjohn adopted by reference Wyeth's argument regarding the proximate cause instruction. *See* Fed. R. App. P. 28(i).

stated that the epidemiologic field accepts promotion as the mechanism by which hormone replacement therapy causes breast cancer. Thus, the instruction was appropriately tailored to the facts. *See Pershern v. Fiatallis N. Am., Inc.*, 834 F.2d 136, 139 (8th Cir. 1987).

The court showed no bias in its instruction. The producing-cause definition reflects Wyeth's theory of the case—that hormone replacement therapy does not initiate the first abnormal cells or turn normal cells into cancerous cells—and is appropriately supported by the evidence Wyeth presented. Scroggin argued promotion, Wyeth argued initiation, and the court instructed the jury on both theories. The court also instructed the jury that it could not award damages for any injury that did not occur as a result of Scroggin's taking Prempro or Premarin and Provera. The instruction contains the substantive requirements of proximate cause; what remains is form and language, which we leave to the court's broad discretion. *In re Prempro Prods. Liab. Litig.*, 514 F.3d at 829.

3. Denial of Wyeth's and Upjohn's Motions for Judgment as a Matter of Law on Proximate Causation

The district court denied Wyeth's and Upjohn's motion for judgment as a matter of law based on their claim that Scroggin did not prove that their failure to warn of the risk of breast cancer proximately caused her breast cancer. We review the denial of their motions *de novo*, "viewing the evidence in the light most favorable to the prevailing party and making all reasonable inferences in favor of the jury's verdict." *Boerner*, 394 F.3d at 598. "Judgment as a matter of law is only appropriate when no reasonable jury could have found

for the nonmoving party." *Mattis v. Carlon Elec. Prods.*, 295 F.3d 856, 860 (8th Cir. 2002). Ordinarily proximate cause is a question of fact, except where the evidence is such that reasonable minds cannot differ. *Ashley County*, 552 F.3d at 667 (citing *Wilson v. Evans*, 679 S.W.2d 205, 206 (Ark. 1984)).

Wyeth and Upjohn argue that the evidence was not sufficient to show that an adequate warning would have prevented Scroggin's breast cancer. The parties disagree about who had the burden to show what effect an adequate warning would have had. Specifically, they argue about the application of the heeding presumption—the presumption that a person would have heeded an adequate warning if given—and whether it applies to pharmaceutical cases. Notably, neither party asked Dr. Kuperman if he would have prescribed the medication to Scroggin if there had been an adequate warning.

Scroggin argues that the heeding presumption is a rebuttable presumption, shifting the burden to Wyeth and Upjohn to show that an adequate warning would not have prevented Scroggin's injuries. Although Arkansas law generally applies the heeding presumption in this manner, see *Smith v. Rogers Group, Inc.*, 72 S.W.3d 450, 458 (Ark. 2002), Arkansas has yet to consider the presumption in a pharmaceutical case. Wyeth argues that the presumption should only imply that the physician would have considered it, but that the burden remains on the plaintiff to show that an adequate warning would have altered the physician's decision to

prescribe the product and the plaintiff's decision to take it.[15]

The Tenth Circuit noted in a pharmaceutical case that "[t]he vast majority of jurisdictions hold that where a warning is inadequate, the plaintiff is entitled to a rebuttable presumption that an adequate warning would have been heeded if one had been given." *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 855 (10th Cir. 2003). Given the current application of the heeding presumption in Arkansas and the majority view, we conclude that Arkansas likely would require Wyeth and Upjohn to rebut the presumption even in a case involving pharmaceutical products. Moreover, Wyeth and Upjohn rely on *Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1019 (10th Cir. 2001) (relying on Oklahoma law), which required the drug manufacturer defendants to rebut the presumption by showing that the additional information "would not have changed the prescribing physician's course of treatment." Wyeth and Upjohn failed to establish that Dr. Kuperman would have prescribed the hormone replacement therapy despite an adequate warning.

Although conflicting, the evidence on proximate causation was sufficient to allow the jury to find that a failure to warn was the proximate cause of Scroggin's

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[15] Wyeth and Upjohn rely primarily on *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806 (5th Cir. 1992). In *Thomas*, the Fifth Circuit acknowledged that no Mississippi Court applied the heeding presumption to a medical drug case, noting that state case law "strongly suggests that a presumption does not exist under Mississippi law." *Id.* at 813. In *Ackermann v. Wyeth Pharms.*, 526 F.3d 203 (5th Cir. 2008), the Fifth Circuit stated that Texas had "explicitly rejected the . . . read-and-heeded presumption." *Id.* at 212-13 (citations and internal quotations omitted).

injuries. Dr. Kuperman testified that he still prescribes estrogen plus progestin to menopausal women and that the initially reported results of the WHI study indicated a slight relationship. On the other hand, his prescription practices for these drugs have changed since the WHI study. Since 2002, Dr. Kuperman has written fewer prescriptions for hormone replacement therapy drugs. Moreover, he tries to keep the prescription duration to below five years, as the breast cancer risk increases with use. Dr. Naftalis testified that Scroggin would not have developed breast cancer if she had taken the therapy for five years rather than eleven. Accordingly, the jury could reasonably conclude that had Wyeth and Upjohn adequately warned of the breast cancer risk, Scroggin would have been among Dr. Kuperman's patients who do not take hormone replacement therapy drugs or among those who take them for a shorter period of time.

Dr. Kuperman also testified that he would respect a patient's wishes and not prescribe hormone replacement therapy if she was concerned about the risk of breast cancer. Thus, the jury could have concluded that Scroggin would have chosen not to take the drugs if the warnings had been adequate. Although Wyeth and Upjohn focus on Scroggin's acknowledgment that she would have accepted a "small" risk and that she did not know that estrogen plus progestin use "causes" breast cancer, the jury was not so limited. The jury heard Scroggin explain her understanding of risk as anything that could possibly happen, even if highly unlikely, and how the equivocal language in the pre-WHI labels reassured her that the risk was small. The current labels do not simply identify the 1.24 relative risk reported from the WHI study, but also include a boxed warning, with straightforward language, and devote substantial attention to the risk of breast cancer. Scroggin testified

that she would not have taken hormone replacement therapy if she had known of the risk as it was currently understood.

D. Punitive Damages

Scroggin's argument during the punitive damages phase of the trial was two fold: (1) Wyeth and Upjohn were aware that estrogen plus progestin could cause breast cancer but had consciously disregarded the risk, and (2) Wyeth downplayed the risk, campaigning against its acceptance within the scientific community, the FDA, and the general population. In support of her argument, Scroggin presented Dr. Parisian as an expert witness on FDA regulations and Wyeth's and Upjohn's lack of compliance therewith.

The district court ordered Dr. Parisian to base her opinion "on her observations over the years and her understanding of the regulations referenced in her expert report, her deposition, and the supplemental briefs." During Dr. Parisian's testimony, the district court expressed frustration that she was not linking her testimony to FDA regulations. Because Dr. Parisian's testimony consisted mostly of her reading documents, and not expert analysis, the district court concluded that "most of Dr. Parisian's punitive damages testimony should have been excluded." Thus, although it had denied Wyeth's and Upjohn's motions to strike during the trial, the district court granted their post-trial motions and struck much of Dr. Parisian's testimony and related exhibits.

Without that evidence, the district court determined that Scroggin "failed to present clear and convincing evidence warranting punitive damages" and granted Wyeth's and Upjohn's motions for judgment as a matter

of law. The district court ruled that if it had not granted those motions, it would have granted a new trial on punitive damages.

1. Post-Judgment Exclusion of Dr. Parisian's Punitive Damages Testimony and Accompanying Exhibits

Scroggin argues that the district court erred in striking Dr. Parisian's testimony. We review a district court's decision to exclude expert testimony for an abuse of discretion. *Larson*, 414 F.3d at 940. Federal Rule of Evidence 702 permits expert testimony to assist the jury in understanding technical or scientific evidence.

As an initial matter, we disagree with Scroggin's contention that Wyeth and Upjohn did not preserve their objection to Dr. Parisian's testimony. The district court stated that the defendants "submitted motions to exclude, lodged numerous objections during the punitive damages stage, and requested, both orally and in writing, that Dr. Parisian's punitive damages testimony be stricken or excluded." That Wyeth and Upjohn did not object during Dr. Parisian's testimony until the court expressed its own concerns did not waive their objection, for as the court noted, "their specific points had been made and were well-known to [the court] and [Scroggin's] counsel."

Dr. Parisian's testimony began with a brief overview of some federal regulations, followed by discussion of specific exhibits, largely devoid of regulatory analysis. The record reflects that often Dr. Parisian simply read the contents of exhibits, thus undermining the asserted basis for expert testimony. At a sidebar conference during the testimony, the district court instructed Scroggin's counsel to relate the testimony to FDA

guidelines; nevertheless, the testimony continued in the same manner. Accordingly, we cannot say that the district court abused its discretion in striking Dr. Parisian's testimony.

2. Grant of Judgment as a Matter of Law Dismissing Jury's Punitive Damages Award

Scroggin asserts that even without the excluded testimony and related exhibits, the evidence was sufficient to support the jury's award of punitive damages. We review *de novo* a court's grant of judgment as a matter of law. *Carter*, 456 F.3d at 846. "Judgment as a matter of law is only warranted where the evidence at trial is wholly insufficient to support a jury finding." *Id.*

Arkansas law allows for punitive damages when a defendant "knew or ought to have known . . . that his or her conduct would naturally and probably result in injury or damage and that he or she continued the conduct with malice or in reckless disregard of the consequences from which malice may be inferred." Ark. Code. Ann. § 16-55-206. "[M]alice is not necessarily personal hate; it is, rather, an intent and disposition to do a wrongful act greatly injurious to another." *Yeakley v. Doss*, 257 S.W.3d 895, 899 (Ark. 2007) (citing *Fegans v. Norris*, 89 S.W.3d 919 (Ark. 2002)). "A claim for punitive damages is properly submitted to the jury under Arkansas law where the claim is supported by substantial evidence." *Morris v. Union Pac. R.R.*, 373 F.3d 896, 903 (8th Cir. 2004) (internal quotations omitted) (citing *D'Arbonne Constr. Co. v. Foster*, 123 S.W.3d 894, 898 (Ark. 2003)).

a. Upjohn

We affirm the district court's grant of judgment as a matter of law to Upjohn. Most of the evidence presented during the punitive damages phase concerned Wyeth, and the evidence related to Upjohn focused on its efforts to market Provera as "the other half of estrogen replacement therapy." These advertisements violated federal regulations, but there is no dispute that prescribing progestin along with estrogen had become the standard of care in hormone replacement therapy. Scroggin also contends that a jury could infer malice because Upjohn failed to conduct an in-house study of the breast cancer risk after the Degge Group found that further study was needed. Upjohn, however, did not conceal or restrict the dissemination of the information. It allowed the Degge Group to publish its findings, thus informing the scientific community of the current state of the science. On this record, then, there was not substantial evidence showing that Upjohn acted with "such a conscious indifference to the consequences that malice may be inferred." *D'Arbonne Constr. Co.*, 123 S.W.3d at 898.

b. Wyeth

We adopt the district court's alternative holding as to Wyeth and remand for a new trial on punitive damages. Scroggin presented sufficient evidence to submit the question of punitive damages to the jury, even without Dr. Parisian's testimony. Moreover, many of the stricken exhibits had been admitted prior to Dr. Parisian's testimony and without any requirement that they be presented in relation to Dr. Parisian's knowledge of FDA regulations. Accordingly, the jury could have considered those exhibits and drawn its own conclusions.

In ruling on the post-verdict motions, the district court set forth a detailed analysis of the evidence, explaining that each piece failed to present clear and convincing evidence of reckless indifference. We conclude that this individualized treatment of the evidence may inadvertently have obscured the full scope of Wyeth's conduct that the evidence collectively portrayed. Although Wyeth's failure to organize one study to allow for adequate evaluation of the breast cancer risk, or its attempts to undermine the results of one adverse publication, may not reflect reckless disregard, a consistent pattern of such conduct might do so. A jury could find that although each study added to the evidence suggesting a risk of breast cancer, Wyeth nevertheless continued to engage in a practice of both inaction and mitigation.

The district court noted that the evidence showed that Wyeth attempted to convey that there was no definitive link between estrogen plus progestin hormone replacement therapy and breast cancer. But Scroggin's claim also rested on the theory that Wyeth deliberately avoided studying hormone replacement therapy's effect on breast cancer. Moreover, a jury could reasonably construe Wyeth's documents as repeated efforts over many years to undermine information and studies that attempted to show a breast cancer link. A jury reasonably could find that these efforts allowed Wyeth to promote the false understanding that hormone replacement therapy was not linked to breast cancer and then to promote reliance on this understanding. Viewed as a whole, then, the evidence presented could allow a jury to find or infer that Wyeth was guilty of malicious conduct within the meaning of Arkansas law.

There is also merit to Scroggin's assertion that the district court characterized certain evidence in Wyeth's favor. In entertaining a motion for judgment as a matter of law, the court "must draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000). The law requires the district court to "disregard all evidence favorable to the moving party that the jury is not required to believe." *Id.* at 151. The court, however, credited Justin Victoria's characterization of Wyeth's response to the 1976 Hoover study, thus ignoring Wyeth's efforts to refute and mitigate the results of the study. Likewise, the documents suggesting that Wyeth had a policy of refusing drug samples for breast cancer studies are not as clear as Wyeth would have the jury believe. These documents, and many of the stricken documents, were Wyeth's internal documents and thus not capable of being rebutted or characterized by Scroggin's witnesses. The jury could have concluded that the documents spoke for themselves and rejected Wyeth's self-interested explanation. *Cf. Wilcox v. State Farm Mut. Auto Ins. Co.*, 253 F.3d 1069, 1070-71 (8th Cir. 2001) (noting that it would not be obvious error to credit employer's affidavit detailing employee's performance deficiencies when employee was given a clear opportunity to contradict the affidavit).

For these reasons, we conclude that there was sufficient evidence upon which a jury could conclude that Wyeth acted with reckless disregard to the risk of injury, even without Dr. Parisian's testimony. The admission and the jury's consideration of Dr. Parisian's testimony, however, amounted to prejudicial error, and thus the appropriate remedy is a new trial. Because a

new trial may be had on punitive damages alone without injustice to the parties, we adopt the district court's alternative judgment granting a new trial to Wyeth on the punitive damages claim. *See Eng. v. Gulf & W. Mfg. Co.*, 728 F.2d 1026, 1029 (8th Cir. 1984) (citing *Gasoline Prods. Co. v. Champlin Ref. Co.*, 283 U.S. 494, 500 (1931)).

We have considered Wyeth's and Upjohn's assertion that a new trial on the liability phase is required due to district court errors and conclude that none of the alleged errors affected Wyeth's or Upjohn's substantial rights.

III. Conclusion

The judgment against Wyeth and Upjohn on Scroggin's claim for compensatory damages is affirmed. The order granting judgment as a matter of law to Upjohn on Scroggin's claim for punitive damages is affirmed. We vacate the order granting judgment to Wyeth on Scroggin's claim for punitive damages, adopt the alternative judgment, and remand the case to the district court for a new trial on punitive damages.

APPENDIX B

UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

No. 08-2555

IN RE: PREMPRO PRODUCTS LIABILITY LITIGATION.

DONNA SCROGGIN, Plaintiff, Appellant,

v.

WYETH, AND ITS DIVISIONS; PHARMACIA & UPJOHN COMPANY, L.L.C., Defendants, Appellees

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December 16, 2009

CORRECTED ORDER

The order entered earlier this date is corrected to read as follows:

The petition for rehearing en banc filed by appellee Wyeth is denied. The petition for rehearing by the panel is also denied.

The petition for rehearing by the panel filed by appellee Pharmacia & Upjohn is denied.

Judge Benton did not participate in the consideration or decision of this matter.

Order Entered at the Direction of the Court:

Michael E. Gans, Clerk
U.S. Court of Appeals, Eighth Circuit

APPENDIX C

UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

No. 03cv1507, No. 04 CV01169

IN RE: PREMPRO PRODUCTS LIABILITY LITIGATION.

DONNA SCROGGIN, Plaintiff,

v.

WYETH, et al., Defendants.

July 8, 2008

WILSON, District Judge.

ORDER[1]

Pending are Defendants' Motion for Judgment as a Matter of Law, or for New Trial, or Remittitur of Punitive Damages Awards (Doc. Nos. 637, 642). Plaintiff

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[1] United States Magistrate Judge Henry L. Jones, Jr. is also assigned to this case and entered some of the orders referenced in this Order.

has responded and Defendants have replied.[2] The parties presented oral arguments on May 9, 2008.

I. BACKGROUND

Following a trial of nearly three weeks, the jury, on February 25, 2008, found that Plaintiff proved by the greater weight of the evidence that Wyeth and Upjohn inadequately warned about a known or knowable risk of Premarin, Prempro, and Provera, and Defendants' failure to warn resulted in Plaintiff's breast cancer.[3] The jury awarded compensatory damages of $2,700,000.00.[4]

The punitive damages phase of the trial commenced on March 3, 2008, and lasted three days. On March 6, 2008, the jury found Defendants liable for punitive damages; Wyeth in the sum of $19,360,000.00 and Upjohn in the sum of $7,760,000.00.[5]

Following the entry of the judgment,[6] Defendants filed Motions for Judgment as a Matter of Law or for a New Trial on both compensatory and punitive damages. As to compensatory damage issues, the motions were denied on April 10, 2008, and the parties were directed to focus their attention on the issue of punitive damages.[7]

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[2] Doc. Nos. 651, 652, 654, 655.

[3] Doc. No. 552.

[4] *Id.*

[5] Doc. No. 616.

[6] Doc. Nos. 629, 636 (correcting the post-judgment interest rate).

[7] Doc. No. 647.

II. STANDARD OF REVIEW

A motion for judgment as a matter of law following a jury verdict — a.k.a. motion for judgment notwithstanding the verdict ("JNOV") — is governed by Federal Rule of Civil Procedure 50. Judgment as a matter of law is appropriate when the evidence, viewed in the light most favorable to the verdict, was such that no reasonable juror could have returned a verdict for the nonmoving party.[8] "Judgment as a matter of law is proper when the record contains no proof beyond speculation to support the verdict."[9] A court should review all of the evidence in the record, including any evidence unfavorable to the non-moving party that "the jury is required to believe."[10]

When considering a Motion for JNOV, a court may reconsider evidence that was erroneously admitted, strike the evidence, and then make the determination as to whether, based on the properly admitted evidence, there was sufficient evidence to support the verdict.[11]

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[8] *Minnesota Supply Co. v. Raymond Corp*, 472 F.3d 524, 536 (8th Cir. 2006).

[9] *Larson by Larson v. Miller*, 76 F.3d 1446, 1452 (8th Cir. 1996).

[10] 9B CHARLES A. WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 2529 (3d ed. 2008) (citing *Reeves v. Sanderson Plumbing Products*, 530 U.S. 133 (2000)).

[11] *Weisgram v. Marley Co.*, 528 U.S. 440, 455-456 (2000) (Finding no abuse of discretion when the appellate court found expert testimony inadmissible and instructed that judgment be entered as a matter of law, since, without the erroneously admitted testimony, there was insufficient evidence to support the jury verdict. The Supreme Court rejected Plaintiff's assertion "that allowing courts of appeals to direct the entry of judgment for defendants will punish plaintiffs who could have shored up their cases by other means had they known their expert testimony would be found inadmissible." The

Additionally, a trial judge who grants a JNOV should rule conditionally on an alternative motion for new trial.[12]

III. DISCUSSION

A. Dr. Parisian's Punitive Damages Stage Testimony

Plaintiff designated Dr. Parisian as her "regulatory expert," and asserted that Dr. Parisian would establish that the duty to test is part of the ordinary care required of pharmaceutical companies.[13] To support her opinions, Dr. Parisian was to rely on her observations over the years as a former FDA medical officer and her understanding of the regulations referenced in her expert report, her deposition and the supplemental briefs."[14]

Defendants repeatedly argued that Dr. Parisian's punitive damages phase testimony should be stricken. Because a court may "satisfy its gatekeeper role" under *Daubert* on a post-trial motion,[15] I will now consider Defendants' Motions to Strike. Incidentally, any assertion by Plaintiff that Defendants did not properly reserve their objections to Dr. Parisian's testimony is without merit. Defendants submitted motions to

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Court recognized that "although [Plaintiff] was on notice every step of the way that [Defendant] was challenging his experts, he made no attempt to add or substitute other evidence.").

[12] *Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 253-54 (1940).

[13] Doc. No. 175.

[14] Doc. No. 389.

[15] *Goebel v. Denver and Rio Grande Western R.R. Co.*, 215 F.3d 1083, 1087 (10th Cir. 2000).

exclude,[16] lodged numerous objections during the punitive damages stage, and requested, both orally[17] and in writing,[18] that Dr. Parisian's punitive damages testimony be stricken or excluded. On an occasion or two, Defendants may have failed to reassert a specific objection contemporaneously, but their specific points had been made and were well-known to me and Plaintiff's counsel.

1. Pre-Trial Limitations on Testimony

Following several rounds of briefing and a hearing, an Order outlining permissible testimony from Dr. Parisian was entered:

> A purely factual recitation of the history of Provera, and its progression as a drug to be used in conjunction with estrogen to treat menopausal symptoms is relevant to show the environment in which Upjohn operated. Use of the specific advertising or promotional pieces is not necessary to make this point. Plaintiff has conceded that Dr. Parisian will not give an opinion on Upjohn's intent or whether Upjohn's advertisement influenced either Plaintiff or any treating physician.
>
> Also Dr. Parisian's testimony is relevant, because she is attempting to show that off-label promotion, without testing, is a violation of pharmaceutical company's duty to use ordinary care . . . Plaintiff's attempt to use Dr. Parisian to establish that the duty

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[16] Doc. Nos. 66, 101,577, 594.

[17] See March 3, 2008, Tr. at 2714; March 3, 2008, Tr. at 2740-41; March 5, 2008, Tr. at 2835; March 6, 2008, Tr. at 2974.

[18] Doc. Nos. 605, 607, 610, 611, 643.

> to test is part of the ordinary care required from pharmaceutical companies, is relevant to the claims in this case. . .
>
> Dr. Parisian has recited her experience in the FDA and the history of Provera, but she has not set out what standards or "standards of the industry" she relies on. As Judge Wilson requested [in his] November 1, 2007 Order, Plaintiff must provide some citation to authority, whether it is legislative or historical, that Dr. Parisian relies on. I have not been able to find such a reference after reviewing her report in the record.
>
> If Plaintiff can provide a specific reference to the standards relied upon by Dr. Parisian, I will reconsider this ruling and address the remaining issues raised in Upjohn's motion.[19]

In response, Plaintiff submitted supplemental briefing, and this order was entered:

> While I agree that Dr. Parisian's citations leave a bit to be desired, I believe she has met the *Daubert* threshold. Defendants' remaining criticism of Dr. Parisian's testimony and report can be addressed during cross-examination.
>
> Dr. Parisian can give her opinions on the reasonableness of a pharmaceutical company's actions based on her observations over the years and her understanding of the regulations referenced in her expert report, her deposition, and the supplemental briefs. Dr. Parisian will not be permitted to talk about or refer to what an "ethical"

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[19] Doc. No. 340 (The Order was entered by Judge Jones).

or "responsible" pharmaceutical company does or would do.[20]

2. Trial Testimony on Regulations

Although she is Plaintiff's "regulatory expert," Dr. Parisian mentioned only three FDA regulations during the punitive damages stage of trial. At the beginning of the punitive damages stage, Plaintiff asked Dr. Parisian whether she had "run across documents that would violate rules that the FDA has regarding how information is to be handled," and she responded, "Yes, sir."[21] Next, Dr. Parisian cited three C.F.R. statutes — two of which Defendants claim were cited erroneously[22] — and summarized the regulations:

> you're supposed to have adequate instructions for use, adequate warnings . . . truthful advertisement, reprints, [and] information that you would provide to your physician . . . marketing information is supposed to be truthful . . . and you're not allowed to have labeling that's false, not fair and balanced.[23]

Following this cursory review of FDA regulations, Dr. Parisian and Plaintiff's counsel commenced addressing specific exhibits.

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[20] Doc. No. 389.

[21] March 3, 2008, Tr. at 2678.

[22] See Doc. No. 643 ("But section 201.105 has to do with veterinary drugs, and section 203 with the reimportation and wholesale distribution of prescription drugs.").

[23] March 3, 2008, Tr. at 2679.

a. December 1975 Dear Doctor Letter (Plaintiff's Ex. 22) and January 1976 Response from FDA (Plaintiff's Ex. 24)

Plaintiff questioned Dr. Parisian about the December 1975 Wyeth "Dear Doctor" letter and the FDA's January 1976 summary of a meeting between Wyeth and the FDA, which discussed this letter.[24] In briefing,[25] Plaintiff asserted that these documents were necessary to "show Wyeth's policy to dismiss and distract, even outright deny, that Premarin causes cancer."[26]

After Dr. Parisian read lengthy passages from the exhibits, Plaintiff's counsel asked "Now, from your expert standpoint, what do those two letters . . . say with regard to Wyeth's knowledge of how to handle scientific data that pertains to their products?"[27] Defendants objected that the question called for speculation and was beyond the scope of Dr. Parisian's report. At the sidebar, I overruled the objection after Plaintiff asserted that Dr. Parisian could "certainly opine about what information FDA requires," how Wyeth responded, and "whether or not that's appropriate under the FDA guidelines."[28] Next, Plaintiff asked Dr. Parisian whether Wyeth "display[ed] a similar attitude as it relates to breast cancer."[29] Again Defendants objected, and it was

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[24] *Id.* at 2681-2685; Plaintiff's Exs. 22 and 24.

[25] Before the punitive damages stage commenced, the parties filed several motions and responses regarding witness, exhibits, *etc.*

[26] Doc. No. 588.

[27] March 3, 2008, Tr. at 2683.

[28] *Id.* at 2684.

[29] *Id.*

overruled. Dr. Parisian testified that rather than "doing scientific studies and addressing the risks [of endometrial cancer, Wyeth] took another route in terms of trying to deal with the problem," and based on the documents she reviewed, there was a similar pattern with breast cancer.[30]

But, Dr. Parisian's testimony did not align with Plaintiff's assurances at the sidebar. Instead Dr. Parisian summarized the document:

> The letter shows that there has been a scientific discussion at the advisory panel meeting and the FDA anticipated that the company, since they are the primary provider of this product, would have pursued a scientific course or some kind of response about a clinical trial doing some kind of study. And that's why the FDA referred to this as a passive position. The company instead chose to tell physicians that it was simplistic and that there was no relation to their product and rather downplayed the risk in terms of addressing it as a responsible manufacturer.[31]

The testimony was simply a regurgitation of an exhibit, absent any expert analysis or opinion. Also missing was any reference to FDA requirements. Despite the assurances of Plaintiff's counsel, Dr. Parisian mentioned neither guidelines nor requirements in her assessment of these two exhibits. Regarding Plaintiff's Exhibits 22 and 24, the record is devoid of any testimony that Wyeth's actions violated FDA regulations or any other defined standard.[32] Instead, Dr. Parisian

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[30] *Id.* at 2685.

[31] *Id.* at 2684.

[32] Notably, Dr. Parisian could hardly testify that Wyeth's action violated FDA regulations, because this position would have been

simply read and summarized the documents, as any layperson could have done. The promised expert testimony simply was not delivered, so I should have struck this testimony at the time.

b. Prempak Study Memo (Plaintiff's Ex. 95)

Next, Dr. Parisian addressed Wyeth's internal minutes of discussions about Prempak and its Prempak Study. Again, she and Plaintiff's counsel took turns reading the document into the record. And, again, Dr. Parisian provided no testimony as a "regulatory expert." As best I can tell, the only reason this document was introduced was to point out that someone at Wyeth wanted to "peek at the data" of the ongoing study. There was no testimony that this would violate any regulations — Dr. Parisian did not testify that this was inappropriate behavior — she stated only that you "have to be careful peeking at the data" so as not to introduce bias.[33] I should not have permitted this evidence.

c. *Seasons* Magazine Proposal (Plaintiff's Ex. 154)

Plaintiff claimed Wyeth's proposal to the FDA regarding *Seasons* magazine established that "Wyeth pushed unapproved long term benefits of E and E+P" but did not study the potential risks of long-term use.[34]

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contrary to the exhibit. The exhibit reads: "This letter is borderline in terms of violating the Food, Drug and Cosmetic Act." The FDA disagreed with Wyeth's actions, but believed only that Wyeth's actions had come close to crossing the line.

[33] March 3, 2008, Tr. at 2688.

[34] Doc. No. 588.

According to Plaintiff, the document "show[ed] Wyeth dismissed and distracted ERT/HRT breast cancer risk and overshadowed any risk of breast cancer with significant long term benefits."[35] Once again, Dr. Parisian read into evidence excerpts from the exhibit and summarized — but her summary required no expertise.

When asked about the letter's meaning "from the FDA's standpoint," Dr. Parisian responded that all manufacturers are supposed to have fair and balanced labeling that's not misleading."[36] Dr. Parisian also testified that when pharmaceutical companies distribute information, it should be clear that the pharmaceutical company is the source of the information, rather than a doctor or pharmacist.[37] Essentially, her testimony mirrored the language in the document. Plaintiff's argument for introducing the document — to show that "Wyeth pushed unapproved long term benefits of E and E+P," but did not study the potential risks of long-term use — was not established by Dr. Parisian. I should have struck the testimony and exhibit, because Dr. Parisian provided no expert analysis.

d. 1993 Premarin Marketing Plan (Plaintiff's Ex. 1565)

According to Plaintiff, the 1993 Premarin marketing plan "show[ed] Wyeth's awareness of long term use of its drugs by many consumers yet Wyeth never chose to study E or E+P long term to evaluate the risks . . . which goes squarely to notice, duty to test, and

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[35] *Id.*

[36] March 3, 2008, Tr. at 2693 (emphasis added).

[37] *Id.* at 2693.

subsequent failure to warn."[38] Defendants suspected that Plaintiff actually intended to use the document to discuss marketing,[39] which is what happened. Dr. Parisian testified that the marketing plan exemplified when a pharmaceutical company's "marketing takes the first seat as opposed to the science."[40] Dr. Parisian's testimony about the document is devoid of any reference to the FDA or reliance on her expertise as an regulatory expert — she provided an editorial about pharmaceutical companies putting sales and marketing before science, but gave no testimony from her position as a regulatory expert. The exhibit should have been excluded.

e. Essner's Prempro Launch Speeches (Plaintiff's Exs. 6776 and 6558)

Plaintiff contended that Bob Essner's April 4, 1995 and April 2, 1995 Prempro "launch" speeches showed "Wyeth's corporate policy to support and push E+P benefits long term without every [sic] studying E+P long term" and how Wyeth treated Prempro "from a risk and benefit perspective."[41]

Basically, Dr. Parisian again read selected excerpts from the documents, but provided no analysis which would require regulatory expertise — or any expertise. There was no mention of FDA regulations, nor any opinion based on her experience as an FDA medical officer. Plaintiff's primary critique of Essner's speeches was that they do not mention short-term use, breast

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[38] Doc. No. 588.

[39] Doc. No. 2703-2704.

[40] March 3, 2008, Tr. at 2704.

[41] Doc. No. 588.

cancer risk, or studies[42] — this was not connected with FDA regulations.

Plaintiff also asked Dr. Parisian about Wyeth's "position with regard to how the product will be treated from a marketing standpoint."[43] In response, Dr. Parisian simply read the exhibit. Had she provided an actual opinion on this topic, it would have been beyond Dr. Parisian's expertise as a regulatory expert. I should have struck the testimony and exhibit.

f. Burson-Marsteller Account Overview (Plaintiff's Ex. 8019-A)

According to Plaintiff, the June 6, 1994 "Burson-Marsteller Premarin & Wyeth-Ayerst Women's Health: Account Overview" exemplified "Wyeth's policy of dismiss and distract of the concerns about the risk of HRT and breast cancer . . . [and] absolutely show[ed] Wyeth was on notice of breast cancer risks but did not study E+P and breast cancer and as a result did not warn of the risk."[44]

Dr. Parisian testified that if a company knew there was a link between its product and breast cancer, neutralizing that information would not be fair and balanced. She continued, "[I]t's the duty of the manufacturer to ensure that the product is safe for that indication and for those women who are using the product."[45]

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[42] March 3, 2008, Tr. at 2707.

[43] *Id.* at 2708.

[44] Doc. No. 588.

[45] March 3, 2008, Tr. at 2712-2713.

Following this testimony, I requested a sidebar, and voiced concern that Dr. Parisian was testifying outside the scope permitted by the pretrial orders. Plaintiff responded:

> [A]s to everything that I've put on thus far, I believe that I've linked it to the FDA regulations. And the concern that's been pointed out by Wyeth even in this most recent document was FDA regulatory concerns. And she went through and described, you know, what would be improper about the approach to neutralizing that evidence. So I don't think I've put in anything that doesn't fit within her area of expertise.[46]

Defendants responded that Dr. Parisian had "gone beyond both her report and her designation for this case and the limits of [pre-trial] ruling[s] regarding her testimony."[47] Plaintiff replied, "Your Honor, this is my only witness. I don't have any other witnesses. You struck Dr. Hollon."[48] Plaintiff's reason for eliciting testimony from Dr. Parisian that was outside of her report was not well founded. If a court strikes one expert, a party may not use another expert to give the same testimony if it is beyond the expert's expertise and designation. I should have struck this testimony.

g. George Mills Email on Breast Cancer Issues (Plaintiff's Ex. 7423)

Plaintiff introduced George Mills's (a Wyeth employee) February 25, 2000 email, which set out his

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[46] *Id.* at 2713.

[47] *Id.* at 2714.

[48] *Id.*

idea for handling breast cancer issues. In the pretrial briefs, Plaintiff asserted that this exhibit "show[ed] Wyeth's policy of dismiss and distract of the concerns about the risks of HRT and breast cancer," and that Wyeth was on notice of a breast cancer risk, but neither studied nor warned of the risk.[49]

Plaintiff's counsel mentioned that he'd previously read the exhibit to the jury, and asked Dr. Parisian if it would "ever be appropriate . . . to withhold information about breast cancer risk from users of the product . . . ."[50] I am unsure as to why a regulatory expert would be needed to explain this document to the jury. The jury was equally capable of assessing the document and making the conclusions offered by Dr. Parisian. In pretrial motions, Wyeth objected on various grounds,[51] and although a specific objection was not interposed during the punitive stage, I should have excluded this exhibit, which was clearly inadmissible via Dr. Parisian (Wyeth repeatedly objected that her testimony was not connected to FDA regulations).

h. February 28, 2000 Budget Proposal (Plaintiff's Ex. 8151)

According to Plaintiff, the February 28, 2000 budget proposal "show[ed] Wyeth's policy of funding to dismiss and distract the risk of breast cancer of E+P while expounding on the long-term benefits of E+P . . . ."[52] Counsel read a section of the exhibit: "In addition, media

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[49] Doc. No. 588.

[50] March 3, 2008, Tr. at 2720.

[51] Doc. No. 566.

[52] Doc. No. 588.

attention on two recent publications have raised consumer awareness about the relative risk of breast cancer . . . Additional funds are needed to minimize the impact on growth or programs which focus on the role of estrogen in disease prevention and help put the small potential risk of breast cancer in perspective."[53] Plaintiff's counsel asked Dr. Parisian, "Would it be appropriate to fund to this degree a campaign that seeks to cut down any media suggestion that there's a breast cancer risk."[54] Dr. Parisian responded, "No. It would not be appropriate from a public health point of view in terms of women's safety."[55] But where was the "regulatory" testimony promised from Dr. Parisian? Wyeth did not lodge a specific objection at this point, but had objected to the exhibit in a pre-trial motion.[56] I should not have permitted the exhibit to be admitted through Dr. Parisian, because she did not connect it with any FDA regulations.

i. Dr. Karla Kerlikowske Study

This is an August 14, 2007 article titled "Declines in Invasive Breast Cancer in Use of Postmenopausal Hormone Therapy in a Screening Mammography Population," by Dr. Karla Kerlikowske, which was published in the Journal of the National Cancer Institute.[57] After Dr. Parisian indicated that she had seen

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[53] March 3, 2008, Tr. at 2721-2722.

[54] *Id.* at 2722.

[55] *Id.*

[56] Doc. No. 566.

[57] Karla Kerlikowske, et al., *Declines in Invasive Breast Cancer and Use of Postmenopausal Hormone Therapy in a Screening*

the document before, Plaintiff asked "can you tell us what Dr. Kerlikowske said regarding the potential risk" of breast cancer.[58] Dr. Parisian read the following to the jury:

> Based on an estimated 211,300 breast cancer cases in 2003, 75 percent of these diagnosed in postmenopausal women, 85 percent of them are ER positive, and an annual decline of 13 percent in ER-positive disease. The impact of declining use of postmenopausal hormone therapy could account for an estimated 17,500 fewer ER-positive invasive breast cancer cases annually among women aged 50 to 69 years.[59]

This testimony on "excess breast cancers" was the subject of numerous oral and written motions. At the close of Dr. Parisian's punitive damages phase testimony, Defendants argued that this "learned treatise" was not properly authenticated by Dr. Parisian.[60] Plaintiff argued that the article was authenticated by Dr. Austin — an epidemiologist and Plaintiff's "general causation expert" — during the compensatory damages phase of trial.[61] While the article may have been authenticated by Dr. Austin, Plaintiff did not establish that Dr. Parisian was qualified to interpret

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Mammography Population, 100 J. OF THE NAT'L CANCER INST. 599 (2008).

[58] March 3, 2008, Tr. at 2722.

[59] March 3, 2008, Tr. at 2722.

[60] March 5, 2008, Tr. at 2837-2838

[61] Doc. No. 652.

it.[62] The evidence from this learned treatise is epidemiologically based and relates to causation; both are outside the scope of Dr. Parisian's qualifications — again, FDA regulations were her designated forte.[63]

"A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty. That would not be responsible science."[64] According to the Advisory Committee notes to Federal Rule of Evidence 803(18), a learned treatise may be admitted as substantive evidence only when "an expert is on the stand and available to explain and assist in the application of the treatise . . . ."[65] As a regulatory expert, Dr. Parisian could not "explain and assist in the application" of the Kerlikowske article to this case. Additionally, Dr. Parisian gave no indication that she relied on the article in forming her regulatory opinions. Accordingly, Dr. Parisian should not have been permitted to read portions of the Kerlikowske article into evidence, and her testimony regarding the Kerlikowske article should have been excluded.

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[62] During a sidebar, I responded that Defendants' objections made me very uncomfortable and made me think I had made pretty clear error. I concluded "I'm going to overrule your motion at this time. I've got it under advisement still." See March 5, 2008, Tr. at 2838.

[63] An expert must establish the trustworthiness of a treatise as viewed by professionals in that field.

[64] *Dura Automotive Systems of Indiana v. CTS Corp.*, 285 F.3d 609, 613 (7th Cir. 2002).

[65] FED. R. EVID. 803(18).

j. CME "Myths and Misperceptions" Handout (Plaintiff's Ex. 427)

This exhibit is a CME course handout titled "Myths and Misperceptions, Breast Cancer and HRT" from September, 1998. Dr. Parisian testified that the FDA would have no ability to restrict these types of CME activities. Since the FDA could not restrict these activities, there was no evidence that Wyeth's actions violated FDA regulations. Accordingly, Dr. Parisian's interpretation of the exhibit was unnecessary.

Furthermore, when Plaintiff used this exhibit, Wyeth objected to "lack of foundation" because the exhibit was "not a Wyeth document."[66] The objection was sustained, but Plaintiff continued to use the document. Allowing further testimony after I sustained the objection was error. It appears that I had my mind in neutral at this point. The testimony regarding this document should not have been admitted.

k. March 4, 1999 Grants Authorizations (Plaintiff's Ex. 5733)

Through Dr. Parisian, Plaintiff introduced Wyeth's finance committee's March 4, 1999 authorization for awards and grants, but all Plaintiff's counsel did with the exhibit was read a few of the names of the organizations on the list.[67] There was no connection between this exhibit and FDA regulations. In fact, the "FDA doesn't have regulations about unrestricted grants."[68] I should have excluded this testimony by Dr. Parisian.

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[66] March 3, 2008, Tr. at 2726.

[67] *Id.* at 2728.

[68] Feb. 20, 2008, Tr. at 2345.

l. Ghostwriting

Dr. Parisian testified that the FDA would not be aware of ghostwriting,[69] and she provided no testimony linking FDA regulations and ghostwriting. Accordingly, I should not have permitted Dr. Parisian to testify on this topic.

m. 1970 Upjohn "Dear Doctor" Letter (Plaintiff's Ex. 5785)

This November 19, 1970 Upjohn "Dear Doctor" letter informed physicians that Upjohn's oral contraceptive, Provest, had been shown to be connected with the "appearance of mammary nodules in beagle dogs exposed to multiples of the human dose of the progestational component for a prolonged period of time."[70] Upjohn relayed to physicians that "[a]ll available clinical data suggest no reason to predict human extrapolation of this finding nor is there any way of disproving that this can occur in the human."[71] Using this exhibit, Dr. Parisian testified only that Upjohn could have arrived at a different conclusion based on the data, and Upjohn could have done its own study to determine the validity.[72] This is more argument than expert testimony. Furthermore, there was no testimony that Upjohn's decision not to conduct a study to refute the beagle dog findings violated any FDA regulations or breached any duty Upjohn might have to test. Dr. Parisian's assessment of this document lacked any

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[69] March 3, 2008, Tr. at 2729.

[70] Plaintiff's Ex. 5785.

[71] *Id.*

[72] March 3, 2008, Tr. at 2731-2732.

regulatory expertise, and I should have excluded the testimony.

n. July 21, 1992 HRT Scientific Review: Executive Session Summary (Plaintiff's Exs. 11011 and 11012)

Through Dr. Parisian, Plaintiff introduced an Upjohn internal memorandum and attachment that described the company's desire to get indications for HRT uses and its strategy going forward. Dr. Parisian simply read a few sections from the document. Since she provided no testimony regarding FDA regulations,[73] the testimony should have been excluded.

3. Necessity of Expert to Distill of Voluminous Documents

In pre-trial briefs and hearings, Plaintiff argued that an expert like Dr. Parisian was necessary to review and summarize documents and "give the jury the tools they need to look at those documents, [and] understand them in the context of a regulatory background."[74] Plaintiff asserted that "Dr. Parisian's testimony and use of internal company document [would] educate the jury, not merely duplicate counsel's closing argument."[75] Plaintiff pointed out that in other bellwether trials I ruled that this was acceptable for trial.[76] In this case, the Court[77]

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[73] March 3, 2008, Tr. at 2736-2739.

[74] Nov. 5, 2007, Tr. at 113.

[75] Doc. No. 175.

[76] Nov. 5, 2007, Tr. at 113 and Doc. No. 175.

[77] I say "the Court," because this Order was entered by Judge Jones.

ruled: "A purely factual recitation of the history of Provera, and its progression as a drug to be used in conjunction with estrogen to treat menopausal symptoms is relevant to show the environment in which [Defendants] operated."[78] The purpose for allowing such testimony was efficiency, and the summary of the documents was to be "purely factual."

Repeatedly, Plaintiff has argued that "[d]istilling voluminous documents is proper" for an expert — but I do not believe the 22 or so documents introduced through Dr. Parisian during the punitive damages stage can be considered "voluminous." But more importantly, and contrary to Plaintiff's position during the *Daubert* hearing, and during he punitive damages stage, Dr. Parisian, generally, did *not* "give the jury the tools they need to look at those documents, [to] understand them in the context of a regulatory background"[79] — she simply read the documents to the jury.

I cannot accept Plaintiff's position that Dr. Parisian "didn't just read a document," but "tie[d] pieces of the puzzle together."[80] To the contrary, Dr. Parisian usually read selected portions of documents in evidence, without further comment. I did not anticipate that documents would be admitted via Dr. Parisian so that she could simply engage in recitation of those exhibits; jurors are capable of reading documents. Ironically, on cross-examination, Dr. Parisian, on at least one occasion, took the position that the document "speaks for itself."[81]

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[78] Doc. No. 340.

[79] Nov. 5, 2007, Tr. at 113.

[80] May 9, 2008, Tr. at 41.

[81] March 3, 2008, Tr. at 2794.

If an expert does nothing more than read exhibits, is there really any point in her testifying as an expert? As was seen during the punitive damages stage, the use of the "regulatory expert" to deal with large volumes of documents is subject to abuse. The expert did not explain the documents, provide summaries, or tie them in to her proposed regulatory testimony. Dr. Parisian did not provide analysis, opinion, or expertise.

4. Applying FDA Regulations to the Facts

In response to Defendants' Motion to Exclude Dr. Parisian's testimony regarding FDA regulations — filed before Dr. Parisian testified during the punitives phase — Plaintiff asserted that Dr. Parisian "will testify further, what those [FDA] regulations require *in a particular set of facts and circumstances*. Dr. Parisian will also testify that the regulations were violated under this set of facts."[82] She did neither. As discussed in detail above, Dr. Parisian often did nothing, or little, more than read exhibits.

5. Summary

Federal Rule of Evidence 702 permits expert testimony to assist a jury in understanding technical or scientific evidence. Dr. Parisian was designated to testify on regulations and the standards and practice in the industry based on her experience. Yet, Dr. Parisian's punitive damages stage testimony was hardly expert in nature. The question and answer sessions merely paid lip service to Dr. Parisian testifying from an expert standpoint.

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[82] Doc. No. 589 (emphasis in original).

The Advisory Committee notes to Federal Rule of Evidence 702 read: "If the witness is relying . . . primarily on experience, then the witness must explain how that experience is a sufficient basis for the opinion and how that experience is reliably accurate to the facts." In pretrial hearings, Judge Jones and I both expressed concern regarding whether Dr. Parisian met this requirement (as evidenced by the repeated requests for citations and explanations[83]). After hearing Dr. Parisian's testimony in the punitive damages phase and reviewing it post-trial. I realize that our concerns were warranted.

Dr. Parisian's punitive damages stage testimony reveals "how vital it is that judges not be deceived by the assertions of experts who offer credentials rather than analysis."[84] "An expert who supplies nothing but a bottom line supplies nothing of value to the judicial process."[85] Expert opinion must be just that — expert opinion drawn from a special expertise. Opinion given through the mouth of an expert does not necessarily make it *expert* opinion.

During the punitive damages stage of the trial, Dr. Parisian's testimony tracked Plaintiff's legal arguments, and there was very little significant analysis. On numerous occasions, Dr. Parisian declared "this isn't fair and balanced," but she provided no explanation. Dr. Parisian, no doubt has special knowledge and skill

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[83] Doc. Nos. 340, 389, and Nov. 14, 2008 email Correspondence from the Court.

[84] *Minasian v. Standard Chartered Bank, PLC*, 109 F.3d 1212, 1216 (7th Cir. 1997) (citations omitted).

[85] *Id.*

regarding FDA operations and regulations, but she did not apply this knowledge and skill to her testimony.

When Dr. Parisian actually elaborated on documents, her testimony did "no more than counsel for plaintiff [did] in argument, *i.e.*, propound a particular interpretation of [defendant]'s conduct."[86] Having an expert witness simply summarize a document (which is just as easily summarized by a jury) with a tilt favoring a litigant, without more, does not amount to expert testimony. Because Dr. Parisian's testimony — or reading — invaded areas that required no expert assistance, it was inappropriate "expert" testimony.[87]

Since Dr. Parisian testified as to the bottom line without any explanation, failed to provide expert analysis, testified beyond limitations established by pretrial orders, testified in areas beyond her expertise, and invaded areas that required no expert testimony, most of Dr. Parisian's punitive damages testimony should have been excluded.

B. Sufficiency of Evidence During Punitive Damages Stage

Excluding the testimony I erroneously allowed in through Dr. Parisian, Plaintiff did not produce sufficient evidence to create an admissible issue under the clear and convincing standard required for punitive damages.

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[86] *In re Rezulin*, 309 F. Supp. 2d 531, 551 (S.D.N.Y. 2004) ("[E]xperts should not be permitted to 'supplant the role of counsel in making argument at trial, and the role of the jury in interpreting the evidence.'").

[87] *Id.* at 541.

The Arkansas Supreme Court has approached punitive damages with caution: "If punitive damages are improperly awarded, the defendant suffers far more than a plaintiff does if the jury incorrectly fails to give him a windfall."[88] In Arkansas, "an award of punitive damages is justified only where the evidence indicates that the defendant acted wantonly in causing the injury or with such a conscious indifference to the consequences that malice may be inferred."[89] To justify an award of punitive damages, "it must appear that the negligent party knew, or had reason to believe, that his act of negligence was about to inflict injury, and that he continued in his course with a conscious indifference to the consequences, from which malice may be inferred."[90] Arkansas law requires an "element of willfulness or such reckless conduct on the part of the defendant as is equivalent thereto."[91] "Gross dereliction of duty does not warrant punitive damages."[92]

In the punitive damages stage, Plaintiff's burden was to establish, by clear and convincing evidence, that Defendants knew or should have known that their negligent failure to warn (which, based on the

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[88] *Nat'l Bank of Commerce v. McNeill Trucking Co., Inc.*, 828 S.W.2d 584, 589 (Ark. 1992) (Dudley, J., concurring).

[89] *Union Pacific R.R. Co. v. Barber*, 149 S.W.3d 325, 343 (Ark. 2004) (citing cases).

[90] *Id.*

[91] *Id.*

[92] *Orsini v. Larry Moyer Trucking, Inc.*, 833 S.W.2d 366, 368 (Ark. 1992); see also *Alpha Zeta Chapter of Pi Kappa Alpha Fraternity by Damron v. Sullivan*, 740 S.W.2d 127, 132 (Ark. 1987) ("Negligence alone, however gross, is not enough to sustain punitive damages.").

compensatory damages phase testimony, included a duty to test) of the risks associated with ERT/HRT use *and* breast cancer would result in injury, and that Defendants continued the conduct with wantonness or reckless disregard from which malice can be inferred.

During opening statements of the punitive damages stage, Plaintiff's counsel argued the evidence would establish that:

> Wyeth and Upjohn failed to follow up on the red flags that showed that this product was causing breast cancer, they failed to get the proper answers by going out and studying the drugs, and they failed to give the doctors and the women accurate information. And then finally, they failed to market the product appropriately.[93]

Yet, the evidence Plaintiff presented was an extension of the liability arguments that amounted to no more than negligence. The record, absent erroneously admitted information, reflects insufficient evidence of wantonness, willfulness, or reckless disregard from which malice could be inferred.

1. Summary of Punitive Damages Evidence Against Wyeth.

Plaintiff's argument for punitive damages can be summarized as follows: In 1976 Wyeth was aware of the Hoover Study, which suggested a link between estrogen use and breast cancer. The endometrial cancer crisis also occurred around this time, and Wyeth should have seen it as a wake-up call to commence looking into the relationship between estrogen use and breast cancer.

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[93] March 3, 2008, Tr. at 2649.

Wyeth knew that physicians were prescribing estrogen and progestin together, and it should have realized that if E-alone causes cancer in one reproductive organ, the addition of progestin could cause cancer in similar organs. Wyeth "knew" adding progestin to estrogen could increase the risk of breast cancer.

Wyeth knew more study was needed, but took a passive role in conducting studies. When Wyeth considered initiating the Prempak Study, Wyeth was concerned that the study might not be successful and could be "embarrassing." Wyeth never completed the Prempak Study.

Wyeth responded to studies associating ERT and HRT use with breast cancer by downplaying the studies and promoting the benefits of ERT and HRT. Specifically, Wyeth used public relations firms, "friendly organizations to which it gave millions of dollars, friends who spoke favorably about its products, marketing, press manipulation or even ghostwriting" to counter studies (and media) reporting a link between HRT and breast cancer.[94]

a. Wyeth Knew About Studies Linking Breast Cancer and Estrogen

Plaintiff argued that in 1976 Wyeth was aware that the Hoover Study[95] suggested a link between estrogen

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[94] Doc. No. 652.

[95] Dr. Hoover wrote a letter to Wyeth that reads:

> Enclosed is a confidential copy of a manuscript which will be published . . . This study forms the basis for my . . . statement that I had evidence which I interpreted as indicating that menopausal estrogens may be a risk factor for breast cancer as well as for endometrial cancer. As you can see, the findings for

use and breast cancer, but "did nothing" in response.[96] This argument is contrary to the evidence in the record. Wyeth acknowledged the Hoover Study and determined that the suggestion of a link between estrogen use and breast cancer "required further evaluation and monitoring, which is what [Wyeth] did."[97] Additionally, Wyeth took the position that it "need[ed] to know all there is to know, both good and bad, about all available studies having a bearing" on the connection between estrogen use and breast cancer.[98] Wyeth recognized that it may need to "shift their efforts to the development of a protocol for a study on mammary cancer."[99]

Three months later, in June of 1976, Wyeth noted that "there have been and are numerous epidemiological studies on the clinical effects of long term estrogen therapy," but concluded that the "studies on estrogen-breast cancer relationships . . . show[ed] no significant increase in the relative risk."[100] Wyeth concluded that "[t]he fact that no recent significant increase in breast cancer has been reported can be taken as an *indirect* indication that estrogens do not cause an increase in

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> breast cancer are certainly not as clear-cut as those for endometrial cancer . . . I believe it does indicate that there may be a problem, that certainly, needs more intensive study.

Plaintiff's Ex. 31.

[96] Doc. No. 652.

[97] Feb. 7, 2008, Tr. at 504.

[98] Plaintiff's Ex. 26.

[99] *Id.*

[100] Plaintiff's Ex. 28.

breast cancer" and that "[e]strogen use does not appear to bring about an increased risk of breast cancer."[101]

In sum, Wyeth's response to the 1976 study suggesting a link between estrogen use and breast cancer — recognition of a possible connection and follow-up research — illustrated neither a passive response nor reckless indifference that would infer malice.

b. Endometrial Crisis Should Have Been A Wake-Up Call

In post-trial briefing, Plaintiff asserted that the "endometrial cancer crisis should have been a wake-up call to Wyeth. If E-alone cause[d] cancer in one reproductive organ, the addition of a new hormone, progestin, could cause cancer in another such organ."[102] I do not recall any expert testifying that, because Wyeth was aware that hormones may cause cancer below the waist, it should have known that hormones could cause cancer above the waist. Without scientifically supported evidence, this statement is nothing more than argument. Even if Plaintiff's position was supported by some evidence, the record reflects that Wyeth reviewed the available science and considered the issue.[103]

c. Wyeth Knew That Adding Progestin Could Increase Risk

In its post-trial brief, Plaintiff argued that "Wyeth knew that the addition of a progestin could increase the

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[101] Plaintiff's Ex. 28 (emphasis in original).

[102] Doc. No. 652.

[103] Plaintiff's Exs. 28, 117, and 1057.

incidence of breast cancer";[104] but the brief lacked a citation to evidence that Wyeth "knew" progestins could increase the incidence of breast cancer. Based on the record, what Wyeth "knew" was that "[t]he possible role of progesterone in the etiology of breast cancer is another area that need[ed] clarification."[105] Additionally, the fact that as late as the mid-1990s the medical community believed that adding a progestin to an estrogen would protect against breast cancer, in the same way it protected the uterus, rebuts Plaintiff's unsupported assertion that Wyeth "knew" just the opposite.[106] Accordingly, Plaintiff's argument that Wyeth knew the addition of a progestin could increase the incidence of breast cancer was unsupported by any significant evidence.

d. Wyeth Knew More Study Was Needed, But Took a Passive Role

Plaintiff asserted that in 1977, Wyeth knew that "more study was needed on the combination product."[107] Dr. Parisian testified that Wyeth took a "passive role" in response to the endometrial cancer crisis.[108] She also testified that Wyeth had a passive attitude in its response to breast cancer: "Instead of doing scientific studies addressing the risks, they took another route in terms of trying to deal with the problem."[109] Notably,

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[104] Doc. No. 652.

[105] Plaintiff's Ex. 28.

[106] Feb. 6, 2008, Tr. at 458-459; Feb. 8, 2008, Tr. at 850-852; Feb. 15, 2008 Tr. at 1811-1812.

[107] Doc. No. 652.

[108] March 3, 2008, Tr. at 2685.

[109] *Id.*

Wyeth objected that Dr. Parisian was "not competent to talk about Wyeth's attitude,"[110] and I overruled the objection. On reflection, this was error.

Plaintiff relied on Plaintiff's Exhibits 22 and 24 for this testimony. However, above I determined that since Dr. Parisian did not connect her testimony on these documents to FDA regulations, the testimony and exhibits should not have been admitted. That being so, there is no evidence to support Plaintiff's position.

e. The Prempak Study

Wyeth began studies of the estrogen and progestin combination in the early 1980s.[111] Specifically, in 1983, Wyeth initiated the Prempak Study. Plaintiff's critique of the Prempak Study was minimal — she introduced speculative evidence regarding "embarrassment," pointed out that someone wanted to peek at the data, and emphasized that the study was not completed. I will address each of these in turn.

i. Study Results Could be Embarrassing

A September 22, 1983, Wyeth internal correspondence titled "PREM-PAK: Desired Labeling and Indications" reads, in part:

> An underlying consideration concerning our overall approach to the FDA concerning PREM-PAK has been the importance of avoiding the problems which could arise if the FDA were to take the position that PREM-PAK is equivalent to a combination drug

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[110] *Id.* at 2684-2685.

[111] Feb. 6, 2008, Tr. at 441-442.

> product of the type requiring demonstration that the combination does more than its components in regard to each indication for the combination product. To attempt such demonstration would be very costly, would take many years, and might in the end not prove successful. In fact, the results of the studies that would be needed could turn out to be embarrassing.[112]

Plaintiff asserted that this exhibit "goes to the heart of this issue of whether or not [Wyeth] had reckless disregard."[113] However, Dr. Parisian's testimony about the exhibit, given during the compensatory damages stage, was limited:

> Q: And what could be embarrassing, from your standpoint as an FDA reviewer, if they did studies?
>
> A: Well, it would be embarrassing, perhaps, if the results weren't positive and you didn't get approved.[114]

Plaintiff argued that this exhibit established that Wyeth was aware that a study might reveal that breast cancer could result when progestin is added to estrogen;[115] however, she provided no evidence to support this position. During trial, Wyeth explained that the exhibit:

> is talking about the FDA combination drug policy, which typically when you combine two products together into a combination, the first product has a

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[112] Plaintiff's Ex. 69.

[113] March 3, 2008, Tr. at 2649.

[114] Feb. 12, 2008, Tr. at 1286.

[115] May 9, 2008, Tr. at 44.

> certain degree of benefit or efficacy and the second product has a certain degree of benefit or efficacy. The expectation is that the combination would have a greater benefit, more efficacy, faster efficacy, better efficacy. In this instance, we were not putting the MPA or the progestin component to estrogen to make it more efficacious, to give it better effect, to relieve vasomotor symptoms faster or better, to improve bone better. It was there to protect the endometrium only.
>
> So what Dr. Perdue is saying is that if FDA or anyone were to expect that this particular combination would have better efficacy, it wouldn't, and so if one were to have that expectation, the results of the study might be embarrassing because it didn't provide greater efficacy. That was never the intent and was not the expectation.[116]

When considering the exhibit in context and based on the evidence as a whole, Plaintiff's position appears to be speculation. This evidence that Plaintiff claimed went "to the heart of this issue of whether or not [Wyeth] had reckless disregard," provided no support for her position on punitive damages.

ii. Someone Suggested Peeking at the Data

The Prempak Study's goal was to show that adding progestin to an estrogen would reduce the risk of endometrial hyperplasia.[117] Wyeth's summary of minutes

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[116] Feb. 7, 2008, Tr. at 641.

[117] March 3, 2008, Tr. at 2687.

— from a meeting held in mid to late 1987[118] — discussing the progress of the Prempak Study reads:

> Objective was to demonstrate that the presence of a progestogen did not add to the detriment of the product . . . Hope [the hyperplasia] is showing up in estrogen alone group. If not, can [sic] kiss the product good-bye . . . Somebody should peek at the data when you reach a certain point. [Wyeth] hides the randomization code.[119]

Regarding testing, Plaintiff's counsel suggested that "it looks like [Wyeth] was doing the right thing, but somebody else within this system wanted to peek at the data."[120] As for peeking at the data, as noted above, Dr. Parisian testified only that "[w]e have to be careful peeking at the data because you can introduce bias . . . ."[121] She did not contend that "peeking at the data" was inappropriate or a violation of any regulations; she suggested only that you must be careful. Additionally, there was no testimony that Wyeth either peeked at the data or introduced bias.

iii. The Prempak Study Was Not Completed

Plaintiff pointed out that the Prempak Study was not completed. In 1988, the Prempak Study ended because

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[118] The document is not dated, but the following is included: "No meeting on this project has been held in the last 12 months (May 1986)." Plaintiff's Ex. 95.

[119] Plaintiff's Ex. 95.

[120] March 3, 2008, Tr. at 2688.

[121] *Id.*

of on-going difficulty obtaining participants.[122] No reckless disregard can be inferred from the fact that the study was never completed.

f. Refusal to Provide Drugs to ECOG (Plaintiff's Exs. 251 and 265)

During the compensatory damages stage, Plaintiff presented two internal Wyeth memos, dated December 8, 1993 and February 9, 1994, regarding Wyeth's refusal to supply Premarin in support of a proposed study by the Eastern Cooperative Oncology Group.[123] According to the documents, Wyeth would not provide drugs for the ECOG study "consistent with company policy."[124] While discussing the December 8, 1993 memo, Plaintiff's counsel argued that Wyeth's "company policy" in 1993 was "not to provide drugs to people that were doing studies on breast cancer."[125] The witness "absolutely disagree[d]" with this statement.[126] Using the February 9, 1994 memo, Plaintiff's counsel again attempted to get the witness to agree that Wyeth had a policy of not supporting breast cancer studies; again, the witness disagreed.[127] The witness later testified that Wyeth's "company policy" at the time was to not study ERT or HRT in patients who had previously been diagnosed with

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[122] Feb. 15, 2008, Tr. at 1864.

[123] Plaintiff's Exs. 251 and 265.

[124] Plaintiff's Ex. 251.

[125] Feb. 7, 2008, Tr. at 552.

[126] *Id.* at 553.

[127] *Id.* at 554.

breast cancer, because this was a "contraindication"[128] for the products.[129]

In its post-trial brief, Plaintiff asserted that since Wyeth provided no document laying out "company policy," a jury has the right to infer that the policy was to not give drugs to breast cancer studies.[130] Plaintiff had the burden of proof, and the testimony was that Wyeth's "company policy" in 1993 was to not support the study because it involved a contraindication. Plaintiff presented no evidence to contradict Wyeth's explanation of the "company policy." Accordingly, the ECOG evidence provided no support for Plaintiff's claim that Wyeth took a passive role in conducting studies.

g. Prempro Pivotal Trial

In 1988, Wyeth submitted a draft to the FDA for what would become the Prempro Pivotal Trial.[131] The Prempro Pivotal Trial "monitored for safety risks, including breast cancer . . . ."[132] Plaintiff conceded that the Prempro Pivotal Trial studied for breast cancer, but argued that it was not long enough.[133] While this may be

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[128] According to the Merriam-Webster on-line dictionary, in medicine, a contraindication is a condition or factor "that makes a particular treatment or procedure inadvisable." Available at: http://www.merriam-webster.com/dictionary/contraindication

[129] Feb. 7, 2008, Tr. at 625.

[130] May 9, 2008, Tr. at 45.

[131] Feb. 7, 2008, Tr. at 642. This study was a one-year, randomized controlled trial designed to "assess the impact on endometrial hyperplasia of the combination product." Feb. 7, 2008, Tr. at 644.

[132] *Id.* at 644.

[133] Feb. 7, 2008, Tr. at 590.

true, I do not believe this is evidence from which reckless disregard can be inferred.

h. Reaction to Adverse Studies and Media

According to Plaintiff, Wyeth's reactions to studies that suggested a link between breast cancer and hormone replacement therapy demonstrated Wyeth's conscious indifference. Plaintiff pointed out that Wyeth used public relations firms, "friendly organizations to which it gave millions of dollars," marketing, press manipulation, and ghostwriting to counter studies (and press reporting on the studies) that suggested a link between HRT and breast cancer.[134]

i. Public Relations Firms

Burson-Marsteller is a public relations firm that has worked for Wyeth since the 1980s.[135] Plaintiff devoted considerable time discussing numerous marketing and public relations suggestions that Burson-Marsteller submitted to Wyeth over the years.

According to Plaintiff, Burson-Marsteller's June 6, 1994 "Premarin & Wyeth-Ayerst Women's Health: Account Overview"[136] showed Wyeth's strategy of "pre-empting negative press [and] offer[ing] the media balanced information."[137] According to the document, this approach "[n]eutralized [the] impact of negative news linking ERT to range of health issues."[138] Dr. Parisian

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[134] Doc. No. 652.

[135] March 5, 2008, Tr. at 2897-2898.

[136] Plaintiff's Ex. 8019-A.

[137] Plaintiff's Ex. 8019-A; March 3, 2008, Tr. at 2928.

[138] Plaintiff's Ex. 8019-A.

testified that *if* it were true that there was a link between the product and breast cancer, this approach would not be "fair and balanced . . . [and] it's the duty of the manufacturer to ensure the product is safe for that indication . . . ."[139] This exhibit referenced activities that occurred from 1989-1991, but, according to another Burson-Marsteller proposal, as late as 1995, there was "no definitive evidence associating breast cancer with estrogen . . . [and] the majority of epidemiological studies [showed] no association between the usual low doses used for ERT and breast cancer."[140]

In 1997, Burson-Marsteller suggested that "[i]n the world of ERT and breast cancer, misperceptions and confusion dominate the emotional issues surrounding breast cancer,"[141] and they wanted "to impact existing attitudes about breast cancer by promoting reality and debunking myths surrounding the issues," to get users or potential users away from the "misperceptions linking HRT and breast cancer."[142] The goal was to provide women with "the correct information on the relationship between breast cancer and HRT . . . ."[143] Dr. Parisian testified that Burson-Marsteller's proposal "wanted to create the desired perception of HRT and breast cancer was not known [sic], but I'm supposedly getting so many benefits that I will not fear breast cancer anymore."[144]

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[139] March 3, 2008, Tr. at 2711-2712.

[140] Plaintiff's Ex. 5677.

[141] *Id.*

[142] *Id.*

[143] *Id.*

[144] March 3, 2008, Tr. at 2715.

She said that the proposal "would not be acceptable" to the FDA because it was not "fair and balanced."[145]

In the proposal, Burson-Marsteller designated the Nurses' Health Study as one of "four primary barriers distorting reality" between breast cancer and HRT.[146] According to Dr. Parisian, if this was how Wyeth viewed the Nurses' Health Study, it should have updated its labeling and marketing to physicians or done a study to determine if there was a link between breast cancer and HRT.[147] Again, however, Dr. Parisian did not bottom her opinion upon FDA regulations — her designated area of expertise.

Plaintiff also introduced an August 22, 1997 Burson-Marsteller proposal titled "Premarin Pre-emptive Plan."[148] Plaintiff's counsel pointed out that the plan wanted to "redefine Premarin's risk profile, [sic] breast cancer, demonstrate that Premarin is not a carcinogen."[149] Yet, there was no testimony explaining what this meant, or why it might be malicious.

Plaintiff presented a July 25, 1994 letter from Burson-Marsteller to Wyeth titled "Breast Cancer & ERT: Risk in Perspective Campaign — Preliminary Recommendations."[150] However, the testimony relating

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[145] *Id.*

[146] Plaintiff's Ex. 5677.

[147] March 3, 2008, Tr. at 2716-2717.

[148] Plaintiff's Ex. 1448.

[149] March 5, 2008, Tr. at 2829.

[150] Plaintiff's Ex. 1030.

to this document was not relevant to a punitive damages issue (I'm still puzzled as to why it was introduced).[151]

Plaintiff introduced Wyeth's 1991 "Premarin crisis preparedness plan."[152] According to the testimony, the document was a "mock exercise" for how "Wyeth could respond to issues."[153] There appears to be nothing per se wrong when a company prepares to respond to negative press.

Essentially, Plaintiff used the Burson-Marsteller documents to suggest that Wyeth's responses to negative media are inappropriate. But the evidence in the record established that Wyeth believed the "media sensationalize[d] negative events,"[154] and that the science conflicted with the media reports. Employing a public relations firm to counter the media is not, in itself, evidence of reckless disregard by the company; rather, it may be a business model employed by most corporations. According to the documents, Wyeth's goal was to put the "risk in perspective" and assure that the media provided "balanced" reports on the science regarding the link between HRT and breast cancer. This seems to be in line with Dr. Parisian's repeated phrase that the FDA requires information to be "fair and balanced." Plaintiff's point is that Wyeth countered the media, rather than embracing it and conducting studies. If true, on this record, it is evidence of, at most,

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[151] See March 5, 2008, Tr. at 2816-2820.

[152] Plaintiff's Exs. 1187, 1188, 1190. See March 5, 2008, Tr. at 2898-2903, 2924-2925.

[153] March 5, 2008, Tr. at 2924.

[154] Plaintiff's Ex. 8019-A.

negligence — not clear and convincing evidence of reckless indifference by Wyeth.

ii. Donations to Friendly Organizations

According to Wyeth's finance committee's March 4, 1999 authorization, Wyeth authorized $18,114,725 for awards and grants as part of the annual budget.[155] The exhibit also listed each of the organizations receiving the awards and grants. Plaintiff emphasized the quantity and scope of Wyeth's donations, but Dr. Parisian conceded that Wyeth's support of ACOG, NAMS, and other medical associations was appropriate.[156] So, this exhibit provides no evidence of reckless indifference. And, as discussed above, I should not have permitted the exhibit to be introduced through Dr. Parisian.

iii. *Seasons* Magazine (Plaintiff's Ex. 154)

Wyeth's *Seasons* magazine was intended for "women taking Premarin with incentives to continue taking Premarin."[157] Plaintiff claimed that Wyeth used *Seasons* magazine to downplay the breast cancer risk while promoting the benefits of HRT.[158] According to Plaintiff, this evidence also goes to Wyeth's state of mind.[159]

In a February 25, 1991 letter, the FDA responded to Wyeth's *Season* magazine proposal, which Wyeth

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[155] Plaintiff's Ex. 5733.

[156] Feb. 13, 2008, Tr. at 1534-1535.

[157] Plaintiff's Ex. 154.

[158] Doc. No. 588.

[159] May 9, 2008, Tr. at 32.

"plan[ned] to use in a direct-to-consumer program . . . ."[160] The "draft [was] submitted to the FDA in advance of and requesting permission to publish it."[161] The FDA believed that the proposed draft was "misleading in that the sponsorship [was] not clearly stated. It intentionally misleads the reader into thinking that her physician [was] somehow responsible for providing it to her."[162] The FDA also pointed out that there were "a number of other potentially false and misleading points in the submitted material."[163]

According to Dr. Parisian, if "Wyeth wanted to do something like [the *Seasons* magazine ad campaign], they would have to clearly indicate that they are the source, and they are trying to sell their own products to the woman."[164] Wyeth responded to the FDA on February 25, 1991:

> It was not our intent to imply to consumers that Seasons [sic] magazine is a commercially available magazine being provided by her physician or pharmacist. We have, therefore, revised all components of the program to clearly state that the program and magazine are produced and distributed by Wyeth-Ayerst.[165]

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[160] Plaintiff's Ex. 154.

[161] March 3, 2008, Tr. at 2749.

[162] March 3, 2008, Tr. at 2690.

[163] Plaintiff's Ex. 154.

[164] March 3, 2008, Tr. at 2693.

[165] Wyeth's Ex. 368.

Wyeth revised the *Seasons* magazine draft and resubmitted it to the FDA.[166] On August 19, 1991, the FDA informed Wyeth that it had "further discussed the revised [*Seasons* magazine] campaign," and had "no objections to [Wyeth] proceeding with this campaign."[167] In the ten years that Wyeth published *Seasons* magazine, the FDA never complained about an issue of *Seasons* magazine "as it was published to the public."[168]

Dr. Parisian only testimony on this exhibit was that when pharmaceutical companies distribute information, it should be clear that the pharmaceutical company was the source of the information, rather than a doctor or pharmacist.[169] The document did not provide proof of reckless indifference. Additionally, the April 16, 1991 letter from Wyeth to the FDA[170] reveals Wyeth's state of mind — there's no need to speculate. Wyeth revised the draft to conform with the FDA's request, and "endeavored to clearly state throughout these pieces that the program and magazine are published and provided by Wyeth-Ayerst Laboratories, makers of Premarin."[171]

If this exhibit suggests malice or reckless disregard, the suggestion is weaker than a $2.00 suitcase — it is not enough standing alone or with the other admissible evidence to create a submissible issue on punitive damages. Furthermore, I unable to discern or divine how

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[166] March 3, 2008, Tr. at 2750.

[167] Wyeth's Ex. 700; March 3, 2008, Tr. at 2750.

[168] March 3, 2008, Tr. at 2750-2751.

[169] *Id.* at 2692.

[170] Wyeth's Ex. 368.

[171] *Id.*

this omission (failing to show who wrote the articles) relates to a failure to warn allegation. Regardless, as discussed in Section III(A)(2)(c) of this Order, I should have struck the exhibit and Dr. Parisian's testimony about the exhibit.

iv. Press Manipulation

In early 1990, Wyeth discovered that Dr. Graham Colditz was going to present a study relating Premarin and increases in the risk of breast cancer. Plaintiff introduced evidence that Wyeth's proposed strategy in response to the study was to "[b]e reactive on the cancer issue. Be prepared to take a responsive stance towards media covering the cancer story with accurate, full and balanced information on the issues presented in proper context."[172] Wyeth also considered "plans for publishing breast cancer study."[173] Neither of these actions, without more, support any inference of reckless disregard by Wyeth.

Plaintiff contended that the February 28, 2000 "Premarin — Additional Marketing Budget" "show[ed] Wyeth's policy of funding to dismiss and distract the risk of breast cancer of E+P while expounding on the long term benefits of E+P . . . ."[174] Additional funds were needed because the current budget did

> not adequately support the additional tactics needed to drive growth, particularly in light of the introduction of four new competitors . . . In addition, media attention on two recent publications have [sic]

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[172] Plaintiff's Ex. 1265.

[173] *Id.*

[174] Doc. No. 588.

> raised consumer awareness about the relative risk of breast cancer . . . Additional funds are needed to minimize the impact on growth or programs which focus on the role of estrogen in disease prevention and help put the small potential risk of breast cancer in perspective.[175]

This document does not bolster Plaintiff's claim for punitive damages. The fact that Wyeth increased the Premarin budget in an effort to "put the small potential risk of breast cancer in perspective" does not support a claim that Wyeth acted with reckless indifference. While "putting the risk of breast cancer in perspective" rather than doing an independent study may support a claim for negligence, it does not rise to the level required for punitive damages.

The record is replete with evidence that Wyeth wanted the media to present "balanced" information.[176] No malice or reckless indifference can be inferred from a company's desire to attempt to assure the media presents "balanced" information, especially when there is on-going debate on an issue.

v. Ghostwriting

Plaintiff focused heavily on the fact that Wyeth, through Design Write, collaborated with authors to have articles written about HRT in a process called "ghostwriting." In closing argument, Plaintiff asserted that ghostwriting is "exactly the type of conduct that

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[175] Plaintiff's Ex. 8151.

[176] Plaintiff's Ex. 1265; Feb. 7, 2008, Tr. at 619, 625; Feb. 12, 2008, Tr. at 1294, 1305; Feb. 20, 2008, Tr. at 2323, 2340; March 3, 2008, Tr. at 2711; March 5, 2008, Tr. at 2928, 2932, 2935, 2956-2957.

necessitates punitive damages."[177] However, there is no evidence that this practice is inappropriate or that Wyeth supported articles that it knew were false or misrepresented the science. Rather, the articles supported Wyeth's position on the state of the science. Additionally, there was evidence that ghostwriting was a common practice in the industry.[178] In fact, Dr. Parisian conceded that she had done ghostwriting on behalf of Johnson & Johnson.[179]

Regardless of the bad inference Plaintiff placed on ghostwriting, it is apparently the norm in the industry,[180] and without evidence that Wyeth lied or misrepresented the science it chose to support, this evidence does not establish malicious behavior that would permit punitive damages. Additionally, this testimony was introduced through Dr. Parisian, but has no link to FDA regulations — Dr. Parisian's area of expertise. And, if the inference of reckless disregard is raised, it is very weak. There is not enough to support submission to the jury taken alone or considered with all the other admissible evidence.

vi. Essner Launch Speech (Plaintiff's Exs. 6558, 6776)

Plaintiff contended that Bob Essner's (a Wyeth executive) April 4, 1995 Prempro "launch speech"[181] to

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[177] March 6, 2008, Tr. at 3025.

[178] Feb. 20, 2008, Tr. at 2343.

[179] Feb. 13, 2008, Tr. at 1533-1534.

[180] "[H]iring third-party professional writers and asking authors to sign those and asking those authors to be responsible for their content is very common practice." Feb. 20, 2008, Tr. at 2343.

[181] Plaintiff's Ex. 6776.

the Wyeth sales team and his April 2, 1995 Prempro "launch speech"[182] showed "Wyeth's corporate policy to support and push E+P benefits long term without ever studying E+P long term" and how Wyeth dealt with "Prempro from a risk and benefit perspective."[183] During post-trial briefing, Plaintiff asserted that the launch speeches showed how "Wyeth illegally tried to hook postmenopausal women on E+P for the rest of their lives."[184] However, when the Essner launch speeches are reviewed in context, they provides little support for Plaintiff's claims for punitive damages.

First, Plaintiff pointed out that nowhere in these launch speeches does Mr. Essner mention short-term use, breast cancer risk, or studies;[185] but, Plaintiff presented no evidence as to why these speeches would require reference to these specific topics. Additionally, according to the testimony, the sales organization "spent the next five days learning about the safety and efficacy of the product."[186]

Second, Plaintiff argued that Mr. Essner instructed the sales force to "thumb its nose at the FDA" and "improperly, if not illegally promote lifetime use for all women."[187] This conclusion is not supported by the evidence. Mr. Essner's comments were:

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[182] Plaintiff's Ex. 6558.

[183] Doc. No. 588.

[184] Doc. No. 652.

[185] March 3, 2008, Tr. at 2707.

[186] March 5, 2008, Tr. at 2888.

[187] Doc. No. 652.

> [Dr. Healy] made the prediction that in the very near future there is going to be a revolutionary increase in the use of hormones to prevent and treat a variety of conditions in older women . . . [Dr. Healy said] that women starting on HRT at menopause and staying on it for the rest of their lives will become the rule, and that this will have a dramatic and positive effect on women's health . . . We have an opportunity to start the HRT revolution that Dr. Healy predicted. We can make real the full promise of HRT to create in the near future a world where the majority of women will start HRT at menopause and continue on it for the rest of their lives. A world where women will get the full medical benefit of replacing the estrogen lost after menopause and the full protective effect of MPA."[188]

Mr. Essner was quoting Bernadine Healy, the former head of NIH, and her opinion that all women should be on HRT. Additionally, nowhere in the speech does he tell the sales force to promote Prempro in this manner; rather, he's suggesting that things look good for Prempro in view of Dr. Healy's predictions on the future of HRT.

Plaintiff also pointed out that Mr. Essner referenced Carrie Smith-Cox's (from Wyeth's marketing department) comments that "for Prempro and Premphase there are no boundaries, no limits."[189] The unrequited testimony regarding the meaning of "no boundaries, no limits" is that Mr. Essner wanted to get the sales force "fired up" about going all-out to promote

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[188] Plaintiff's Ex. 6558.

[189] March 3, 2008, Tr. at 2707.

Prempro;[190] the phrase was about the sales force's "selling effort."[191]

But, as discussed earlier in detail, I should have struck these two exhibits and Dr. Parisian's testimony about the exhibits.

vii. IARC Document (Plaintiff's Ex. 146)

Plaintiff contended that Wyeth wanted to "ensure that IARC [did] not develop a position on a definitive relationship between breast cancer and estrogen replacement therapy . . . ."[192] Plaintiff argued that this is "not appropriate,"[193] but Plaintiff provided no testimony to support this position — only argument of counsel. In fact, the only point Plaintiff made with this exhibit (that wasn't in opening statement or closing argument — which are not evidence) was that it referred to estrogen therapy alone.

There is no testimony that Wyeth's forming a task force to "provide the necessary information to IARC"[194] to support Wyeth's position that there was no *definitive* relationship between estrogen therapy and breast cancer is improper. If Wyeth believed that there was no "definitive association" between estrogen replacement therapy and breast cancer, why wouldn't it attempt to gather science and convince IARC that there was no "*definitive* association" between the two?

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[190] March 5, 2008, Tr. at 2887.

[191] Plaintiff's Ex. 6776.

[192] Plaintiff's Ex. 146 (emphasis in original).

[193] March 3, 2008, Tr. at 2650.

[194] Feb. 7, 2008, Tr. at 547-548.

2. Summary of Punitive Damages Evidence Against Upjohn

Plaintiff contended that Upjohn was liable for punitive damages because it conducted no studies and proposed no warnings to the FDA regarding the possible connection between Provera use and breast cancer. Plaintiff's position was:

As early as 1963, Upjohn should have been aware of the breast cancer risk related to Premarin, based on an abstract that was released. In 1966, the FDA rejected Upjohn's supplemental new drug application for "revised labeling to include the adjunctive use of [Provera] in hypoestrogenic states."[196] According to Plaintiff, when the FDA informed Upjohn that the "supplemental application [was] incomplete" because it "failed to include adequate clinical data . . . ."[196] Upjohn was on notice of its duty to test the relationship between Provera and breast cancer. In 1970, Upjohn knew that animal toxicology studies, involving a product that was different from Provera, but that contained medroxyprogesterone, reported that the subjects developed mammary nodules. But rather than test, Upjohn informed doctors that "[a]ll available clinical data suggest no reason to predict human extrapolation of this finding nor is there any way of disproving that this can occur in the human."[197] In the 1980s and 1990s, Upjohn promoted Provera as "the other half of estrogen replacement therapy," and the FDA scolded Upjohn when some advertisements attempted to promote

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[196] Plaintiff's Ex. 10388.

[196] *Id.*

[197] Plaintiff's Ex. 5785.

Provera for indications (prevention of endometrial hyperplasia, osteoporosis) for which it was not approved. During this entire time, Upjohn never conducted its own study addressing the breast cancer in connection with HRT.[198]

a. 1963 Upjohn Memo (Plaintiff's Ex. 10388)

Plaintiff asserted that "Upjohn knew of the potential breast cancer risk at least by 1963,"[199] and should have started studying the drug. In June, 1963, Upjohn analyzed an abstract titled "Provera-induced hypercalcemia in women with advanced breast cancer."[200] But this document does not support Plaintiff's suggested inference. The uncontradicted testimony is that the report suggested progestin may have raised calcium levels in women who *already had* breast cancer.[201]

b. "The Other Half of Estrogen Replacement Therapy"

During the punitives stage, Plaintiff's punitive damages evidence against Upjohn focused primarily on correspondence between the FDA and Upjohn regarding advertising campaigns for Provera. Plaintiff argued that this evidence established a duty to test — *e.g.*, "If a drug company advertises its products to be used in combination with another product, the company has a

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[198] March 3, 2008, Tr. at 2738-2739; March 5, 2008, Tr. at 2813.

[199] Doc. No. 651.

[200] Plaintiff's Ex. 10910.

[201] Feb. 19, 2008, Tr. at 2199-2201 and 2226.

duty to study the two drugs in operation together."[202] The evidence was:

- **January 5, 1984 FDA Letter** — The FDA requested "immediate cancellation" of an advertisement that "impl[ied] the use of Provera with estrogen replacement therapy except in those situations as described in [the] approved package insert."[203] The FDA also informed Upjohn that it recognized that the concurrent use of estrogen and progestin was becoming a more common practice, but that Upjohn needed to update its package insert before promoting Provera for such a use.[204]

- **September 10, 1985 FDA Letter** — The FDA wanted ads titled "The other half of estrogen replacement therapy" removed from circulation, because the ads "present[ed] Provera as being safe and effective for the treatment and reversal of endometrial hyperplasia which [was] not an approved indication . . . ."[205] Plaintiff argued that this exhibit establishes that in 1985 Upjohn was aware that its product was being used with estrogen and was under a duty to test.

- **July 10, 1986 Letter** — Upjohn informed the FDA that it planned to submit a proposal for a "convenience pack" for concomitant estrogen and

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[202] Doc. No. 651.

[203] Plaintiff's Ex. 10154.

[204] *Id.*

[205] Plaintiff's Exs. 10178 and 10155 (same document).

progestin administration.[206] The FDA informed Upjohn that "there [was] not yet an indication for such combinations and the potential risks [were] not yet resolved."[207]

- **January 15, 1988 FDA Letter** — Upjohn wanted Provera approved to oppose the endometrial effects of estrogen in menopausal women receiving estrogen replacement therapy. The FDA informed Upjohn that it "failed to provide substantial evidence consisting of adequate well-controlled studies . . ." that Provera will have this effect.[208] Dr. Parisian testified only that the FDA believed that there was insufficient evidence to support the indication Upjohn wanted.

- **October 30, 1990 FDA Letter**[209] — This exhibit was admitted into evidence, but Plaintiff never discussed it with a witness.

- **October 31, 1990 FDA Letter** [210] — The FDA informed Upjohn that it should voluntarily withdraw a promotional piece that suggested that combination estrogen and progestin therapy is indicated to reduce the risk of postmenopausal osteoporosis, because Provera was not indicated for that use.

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[206] Plaintiff's Ex. 10342.

[207] *Id.*

[208] Plaintiff's Ex. 10166.

[209] Plaintiff's Ex. 10180.

[210] Plaintiff's Ex. 10179.

- **November 13, 1990 FDA Letter** — The FDA rejected Upjohn's proposed ads based on the ads' "emphasis . . . on 'menopausal therapy' rather than on an approved product indication."[211] On November 9, 1990, Upjohn informed the FDA that "the relevant promotion pieces and reprints [were] no longer being distributed by sales representatives."[212]

- **December 9, 1991 FDA Letter** [213] — In response to a proposed advertisement from Upjohn, the FDA reminded Upjohn that Provera was not "indicated for use in postmenopausal replacement therapy for the prevention of endometrial hyperplasia."[214]

- **December 13, 1991 FDA Letter** — The FDA informed Upjohn that referring to a postmenopausal patient as a candidate for using Provera is "potentially misleading to the reading regarding the indication for use of the product."[215]

Plaintiff asserted several purposes for this evidence. In pre-trial responses to Upjohn's objections to the exhibits, Plaintiff argued that the exhibits showed Upjohn's policy of promoting "Provera to be used in combination with Premarin without an indication or

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[211] Plaintiff's Ex. 3401.

[212] Upjohn's Ex. 928.

[213] Plaintiff's Ex. 10189.

[214] Plaintiff's Ex. 10189.

[215] Plaintiff's Ex. 10189.

approval to do so."[216] According to Plaintiff, the advertisements "demonstrate[d] Upjohn's failure to study and to warn, and tie[] directly to FDA violations."[217] Plaintiff repeatedly argued that Upjohn calling Provera "the other half of estrogen [replacement] therapy" after being reprimanded by FDA amounted to conscious disregard on the part of Upjohn to follow the rules of the FDA.[218] And, again during the hearing on Defendants' Motions for JNOV, Plaintiff argued that the FDA "repeatedly admonished" Upjohn for advertisements promoting Provera as "the other half of hormone therapy" [sic].[219] But, in its opposition to Defendant's Motion for JNOV, Plaintiff argued that the advertisements "simply triggered Upjohn's duty to study."[220] Regardless of the intended purpose of the evidence, the evidence was merely an extension of the liability phase. At best, this evidence went to a duty to test, which was a compensatory damages stage issue.

If Plaintiff's final position is that the exhibits established a duty to test, then the exhibits are no help in determining punitive damages. First, as stated, this is a compensatory damages stage issue. Second, Plaintiff conceded that "Upjohn was doing studies during this time frame of the endometrial effects of the combination drugs,"[221] but argued that Upjohn was not conducting the "right" studies.

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[216] Doc. No. 588.

[217] Doc. No. 588.

[218] Feb. 19, 2008, Tr. at 2216; Feb. 14, 2008, Tr. at 1604-1605.

[219] May 9, 2008, Tr. at 55.

[220] Doc. No. 651.

[221] March 3, 2008, Tr. at 2734.

To the extent that these exhibits are intended to establish Upjohn's alleged reckless indifference, the inference is not supported by the record. A review of the exhibits shows that the FDA's criticisms were quite specific. Never did the FDA criticize Upjohn's use of the phrase "the other half of estrogen replacement therapy"; rather, the FDA criticized the indications for use suggested by the advertisements. Specifically, the FDA scolded Upjohn for suggesting progestin prevented endometrial hyperplasia,[222] provided protection against osteoporosis,[223] and was safe and effective for treatment and reversal of endometrial hyperplasia.[224]

In summarizing these exhibits, Dr. Parisian testified that Upjohn was "ignoring the FDA" and "providing labeling that's misleading, that's false and misleading, with inadequate instruction for use."[225] This testimony is also essentially unsupported by the evidence. First, the documents involve advertising, not labeling. Second, there is no evidence establishing that Upjohn ignored the FDA. These letters were a dialogue between the FDA and Upjohn regarding appropriate advertising. The FDA informed Upjohn that an ad was "potentially misleading," and Upjohn changed the advertisements. Based on the sum of the testimony at trial, this is the normal course of business.

Dr. Parisian elaborated that "Upjohn is not doing the clinical trials. If you want that indication, you need to do the clinical trials to support that indication and get

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[222] Plaintiff's Ex. 10189.

[223] Plaintiff's Ex. 10179.

[224] Plaintiff's Exs. 10178 and 10155.

[225] March 3, 2008, Tr. at 2736.

approved . . . ."[226] But this doesn't establish malice, without evidence that Upjohn knew or should have known that ingesting progestin would cause breast cancer. At this time (mid 1980s) it was the standard of care in the medical community to prescribe Provera to prevent uterine bleeding and uterine cancer.[227] Although this was the standard of care, prevention of uterine cancer was not an approved indication.[228]

According to Dr. Parisian, if Upjohn "wanted that indication," it needed "to do a clinical study and submit an application to the FDA for approval."[229] Plaintiff asked "while we know that Upjohn was doing studies during this time frame of the endometrial effects of the combination, in all of the documents that you've reviewed, did Upjohn ever do any breast cancer studies during that time frame"; Dr. Parisian responded "No."[230] However, if Upjohn was relying on other breast cancer studies or data, this would not establish malice or reckless disregard.

Finally, if these exhibits were submitted under the negligence standard, they *might* pass muster for jury consideration, but not under the clear and convincing standard.

c. Response to the Degge Group Findings

Plaintiff argued that Upjohn's response to the Degge Group findings "is the most telling proof of Upjohn's

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[226] March 3, 2008, Tr. at 2736.

[227] *Id.* at 2790.

[228] *Id.* at 2791.

[229] *Id.* at 2733.

[230] *Id.*

abject refusal to examine the breast cancer issue . . . ."[231] Following the release of the Bergkvist article,[232] Upjohn retained the Degge Group to conduct a review of the literature on the link between breast cancer and estrogen and progestin use.[233] Based on their review of the literature, the Degge Group determined that the "ultimate effect of progestins on the development of human breast cancer is still unclear . . . ."[234] The Degge Group also determined that additional study was needed, and listed numerous case control studies and cohort studies that were on-going.[235] This report was published in 1992.[236] Plaintiff argued that Upjohn did nothing in response to the Degge Group's report.[237] By "Upjohn did nothing," Plaintiff's point is that Upjohn failed to do an "in-house" study.[238] Dr. Parisian was asked "did Upjohn ever do one thing . . . to find out the effect of MPA in combination with estrogen on breast cancer," and she responded "No."[239]

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[231] Doc. No. 651.

[232] Dr. Parisian testified that the first study that she could recall showing an increased risk of breast cancer when progestins and estrogens are used — as opposed to estrogen alone — was the Bergkvist Study, which was published in 1989. However, Dr. Parisian admitted that Bergkvist was not statistically significant. Feb. 13, 2008, Tr. at 1449.

[233] Feb. 15, 2008, Tr. at 1455; Feb. 19, 2008, Tr. at 2167.

[234] Plaintiff's Ex. 10116.

[235] Feb. 19, 2008, Tr. at 2168; Plaintiff's Ex. 10116.

[236] Feb. 19, 2008, Tr. at 2167-2168.

[237] Doc. Nos. 166, 651.

[238] March 3, 2008, Tr. at 2738-2740; March 5, 2008, Tr. at 2986-2987, 2993.

[239] March 3, 2008, Tr. at 2738.

Plaintiff's focus on the fact that Upjohn did not do its *own* breast cancer studies is of no consequence. This is argument, unsupported by the evidence — there is no evidence that Upjohn was required to conduct its own "in-house" study. Additionally, Dr. Parisian did not reference any FDA regulations that require a pharmaceutical company to conduct an "in-house" study. In fact, as the agreed-to jury instruction points out, Upjohn's duty was "to test *or otherwise discover* risk about which a manufacturer should warn."[240] The unrebutted evidence was that pharmaceutical companies can monitor and rely on the research of independent investigators, rather than conduct their own studies.[241] So, Plaintiff's argument regarding Upjohn's own, in-house study falls well-short of creating a jury issue under the clear and convincing standard.

3. Summary of Evidence During Punitive Damages Stage

In Arkansas, a punitive damages claim "is properly submitted to the jury . . . where the claim is supported by 'substantial evidence.'"[242] Since this case lacked substantial evidence, I should not have submitted the punitive damages issue to go to the jury. Plaintiff presented evidence of what, at first blush, might be considered unsavory practices (*e.g.*, ghostwriting, advertising, countering negative press, *etc.*), but it falls short of establishing a submissible jury issue.

Plaintiff's burden was to show, by clear and convincing evidence, that Defendants knew or should

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[240] Doc. No. 554 (emphasis added).

[241] Feb. 19, 2008, Tr. at 2214.

[242] *Morris v. Union Pacific R.R.*, 373 F.3d 896, 903 (8th Cir. 2004).

have known of the consequences of their actions, and in the face of this knowledge continued a course with such abhorrent indifference to the consequences that malice can be inferred. But the evidence in this case establishes, at most, negligence. Defendants were aware of an association between estrogen and endometrial cancer in the late 1970s. Defendants knew that physicians were starting to prescribe progestin with estrogen in an effort to protect the endometrium. In the late 1970s and early 1980s, the scientific community believed that prescribing progestin to women on estrogen reduced the risk of endometrial hyperplasia.[243] By 1983, ACOG and OB-GYNs endorsed this idea, and the position was held steadfastly throughout the 1980s, 1990s, and today.[244] Additionally, the medical community believed, throughout the 1980s and into the mid-1990s,[245] that progestin protected women taking estrogen from breast cancer.[246]

Plaintiff conceded that the breast cancer risk associated with estrogen plus progestin had not been

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[243] Feb. 19, 2008, Tr. at 2136.

[244] March 3, 2008, Tr. at 2789.

[245] See Feb. 13, 2008, Tr. at 1461 (Dr. Parisian agreed that up until 1995, "there was still an operating assumption and belief that progestins would reduce the risk of breast cancer posed by estrogen alone . . . .").

[246] Feb. 19, 2008, Tr. at 2165, 2230. Dr. Gambrell published an article in 1983 that suggested a reduced risk of breast cancer in women who were on the combination of estrogen and progestins. Feb. 19, 2008, Tr. at 2210. Also, Dr. Dey testified that Wyeth conducted internal research, that it shared with the FDA, that "found that some of the components in Premarin protected against breast cancer." March 5, 2008, Tr. at 2896. This testimony was unimpeached.

accepted when she ingested the drugs, but argued that this "has no bearing on [Defendants'] failure to study."[247] While it may have no bearing on a failure to study, it goes to the heart of the punitive damages issue — did Defendants know or should they have known?

Plaintiff asserted that had Defendants done the "right" studies, they would have uncovered the breast cancer risk long ago.[248] Again, this is compensatory phase argument; punitive damages require much more — clear and convincing evidence of reckless disregard is a heavier burden. Plaintiff's attacks on the inadequacies of the studies relied on by Defendants provide little support for punitive damages. There was no evidence that Defendants knew the studies they conducted or relied upon were inadequate to support their position on the breast cancer issue; and sufficient evidence of reckless disregard is missing.

Upjohn repeatedly attempted to get advertisements approved that suggested indications that had not been approved for Provera. Upjohn submitted the ads, the FDA reviewed the ads, and the FDA rejected them; this appears to be how the process works between the FDA and pharmaceutical companies. Evidence that the FDA scolded Upjohn four or five times, over 20 years, because its proposed advertisements were overly broad, does not establish reckless indifference — this might be different had Upjohn acted contrary to the FDA's criticisms.

Wyeth used advertising to promote estrogen and progestin products. Wyeth also considered suggestion from a public relations firm on how to respond to studies

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[247] Doc. No. 651.

[248] *Id.*

that reflected poorly on its products and present the media with balanced report of the facts. These actions, standing alone or when considered with the other evidence in this case, do not establish reckless disregard.

Once again, to warrant punitive damages, Plaintiff's burden was to prove, by clear and convincing evidence, that: (1) Defendants knew or should have known, in light of the circumstances at the time, that not testing and warning would naturally and probably result in injury; and (2) Defendants continued to not test and warn with reckless disregard for the consequences from which malice can be inferred.[249] Plaintiff's evidence established neither.

CONCLUSION

Based on the findings of fact and conclusions of law above, Defendants' Motions to Strike Dr. Parisian's testimony from the punitive damages phase is GRANTED in PART, and her testimony is STRUCK, as outlined above. Absent the improperly admitted testimony, there is insufficient evidence for a punitive damages award.

Because Plaintiff failed to present clear and convincing evidence warranting punitive damages, Defendants' Motions for Judgment as a Matter of Law (Doc. Nos. 637, 642) are GRANTED as to punitive damages, and the punitive damages awards are VACATED.

If Defendants' Motion for Judgment as a Matter of Law had not been granted, they, at least, would be

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[249] *D'Arbonne Constr. Co., Inc. v. Foster*, 123 S.W.3d 894 (Ark. 2003).

entitled to a new trial on punitive damages. Accordingly, in the alternative, Defendants' Motion for New Trial is GRANTED.

Plaintiff's Motions for Taxation of Costs (Doc. No. 631) is DENIED without prejudice. The motion should forthwith be modified in consideration of this Order as well as the concessions Plaintiff made in her May 5, 2008 reply.[250]

Since I have a deep and abiding faith in randomly selected juries, I am always reluctant to set aside a jury finding. This jury was very attentive throughout. I admitted much evidence that should not have been admitted. The fault is mine alone.

IT IS SO ORDERED this 8th day of July, 2008.

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[250] Doc. No. 653.

APPENDIX D

UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

No. 03cv1507; No. 04 CV01169

IN RE: PREMPRO PRODUCTS LIABILITY LITIGATION.

DONNA SCROGGIN, Plaintiff,

v.

WYETH, et al., Defendants.

November 21, 2007

WILSON, District Judge.

ORDER

1. Defendant's Objections[1] **to the Order of Magistrate Judge** (Doc. No. 388) is OVERRULED.

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[1] I have viewed Defendant's objections as an appeal of Judge Jones's Order. Local Rule 72.1 (VII)(B) reads:

> In all matters delegated under authority of 28 U.S.C. § 636(b)(1)(A), a Magistrate Judge's decision is final and binding and is subject only to a right of appeal to the District Judge to whom the case has been assigned. A party may appeal the

Having given United States Magistrate Judge Jones's Order personal scrutiny, I find it entirely appropriate. (I note parenthetically that the tone of the Objections seem to be at least a mite troublesome).

2. Defendant's Motion for Summary Judgment Re: Failure-to-Warn Claims (Doc. No. 358) is DENIED, based on Judge Jones's November 21, 2007 Order[2] permitting Dr. Parisian to testify — which I adopt, here and now.

However, only Dr. Parisian will be permitted to testify on this, and only to the extent permitted by Judge Jones's Order. I note that my November 1, 2007 Order[3] directed Plaintiff to provide supplemental authority to support her opposition to Defendants' Motions to Exclude Testimony Re: What the "Reasonable" or "Ethical" Pharmaceutical Company Would Do. The only supplemental authority presented was on behalf of Dr. Parisian, in response to Judge Jones's directions. Accordingly, Dr. Parisian is the only expert who will be allowed to address this subject.

Magistrate Judge's ruling by filing a motion within ten (10) days of the Magistrate Judge's decision unless shorter period is set by the District Judge or Magistrate Judge. Copies shall be served on all other parties and the Magistrate Judge from whom the appeal is taken. The motion shall specifically state the rulings excepted to and the basis for the exceptions. The Court may reconsider any matter *sua sponte*. The District Judge shall affirm the Magistrate Judge's findings unless he finds them to be clearly erroneous or contrary to law.

[2] Doc. No. 389.

[3] Doc. No. 326.

3. **Plaintiff's Motion for Extension of Time to Respond to Defendant's Motion for Summary Judgment Re: Failure-to-Warn Claims** (Doc. No. 395) is DENIED as MOOT.

4. **Upjohn's Renewed Motion for Summary Judgment Regarding Plaintiff's Use of Ogen** (Doc. No. 368 is GRANTED. Plaintiff has filed to establish that the Supply Agreement subjected Upjohn to liability for injuries allegedly caused by ingestion of Ogen.

IT IS SO ORDERED this 21st day of November, 2007.

APPENDIX E

UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

No. 03cv1507; No. 04 CV01169

IN RE: PREMPRO PRODUCTS LIABILITY LITIGATION.

DONNA SCROGGIN, Plaintiff,

v.

WYETH, et al., Defendants.

November 15, 2007

JONES, United States Magistrate Judge.

ORDER

Pending are Defendants' Motion to Exclude Expert Testimony of Dr. Robert Fincher (Doc. No. 105), Motion to Exclude Expert Testimony of Dr. Elizabeth Naftalis (Doc. No. 113), and Motion to Exclude Expert Testimony of Dr. Matthew Hollon (Doc. No. 109). Oral argument was heard on November 5-6, 2007, and the parties filed

supplemental briefs and responses on November 9 and 11.[1]

Also at issue is Dr. Austin's testimony on the development of breast cancer at the cellular level, since Plaintiff filed a supplemental brief (Doc. No. 352).

I. STANDARD

A. Burden of Proof

The admission of expert testimony is governed by Rule 702 of the Federal Rules of Evidence, which reads:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.[2]

When a party proffers an expert witness, deciding whether Rule 702 is satisfied is a preliminary issue governed by Federal Rule of Evidence 104(a).[3] Rule 104(a) requires the proponent of evidence to establish its admissibility by a preponderance of the evidence.[4] In

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[1] Doc. Nos. 342-345, 347.

[2] Fed. R. Evid. 702.

[3] *U.S. v. Martinez*, 3 F.3d 1191, 1196 n.10 (8th Cir. 1993).

[4] *Bourjaily v. U.S.*, 483 U.S. 171 (1987).

determining admissibility, the court is not bound by any of the rules of evidence, except with regard to privilege.[5]

B. Legal Standard for Admissibility

The central inquiry under Rule 702 is whether the proffered expert's testimony is sufficiently reliable.[6] The trial court serves a gatekeeping function, ensuring that any expert testimony is reliable and relevant.[7]

To be admissible, expert testimony must satisfy the two prongs of Rule 702.[8] First, it must be based on scientific, technical, or other specialized knowledge.[9] If the testimony is scientific, it must be grounded in the methods and procedures of science.[10] Likewise, "knowledge" requires more than a subjective belief or an unsupported speculation, requiring instead an appropriate level of validation.[11] Second, the testimony must be relevant, in that it must help the trier of fact either understand the evidence or determine a fact in issue.[12] The burden of establishing relevancy and

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[5] Fed. R. Evid. 104(a).

[6] *First Nat'l Bank v. Benham*, 423 F.3d 855, 861 (8th Cir. 2005).

[7] *Id.*

[8] *U.S. v. Cawthorn*, 429 F.3d 793, 799 (8th Cir. 2005).

[9] *Id.*

[10] *Id.*

[11] *Id.* at 799-800 (quoting *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 590 (1993)).

[12] *Id.* at 799.

reliability rests on the proponent of the expert testimony.[13]

Courts have used a variety of factors to determine the reliability of proffered expert testimony. The most frequently discussed factors are those derived from the Supreme Court's opinion in *Daubert*, where the Court established that the trial court may consider:

> (1) whether the theory or technique can be or has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether the theory or technique has a known or potential error rate and standards controlling the technique's operation; and (4) whether the theory or technique is generally accepted in the scientific community.[14]

Because the inquiry is "flexible and fact-specific, a court should use, adapt, or reject *Daubert* factors" as needed based on the facts of a particular case.[15]

The most recent amendments to Rule 702 added three general standards for courts to use in determining the reliability and relevance of proffered expert testimony. First, the proffered testimony must be based on sufficient facts or data.[16] Second, it must be the product of reliable principles and methods.[17] Third, the

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[13] *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 278-78 (5th Cir. 1998).

[14] *Benham*, 423 F.3d at 861 (citing *Daubert*, 509 U.S. at 593-94).

[15] *Unrein v. Timesavers, Inc.*, 394 F.3d 1008, 1011 (8th Cir. 2005).

[16] Fed. R. Evid. 702(1).

[17] Fed. R. Evid. 702(2).

expert must have applied those principles and methods reliably to the facts of the case.[18]

The focus is not on the expert's conclusion, but on the methodology.[19] The proponent of the testimony "need not prove . . . that the expert's testimony is correct, but . . . must prove by a preponderance of the evidence that the testimony is reliable."[20] Determining the validity of an expert's conclusions is the duty of the finder of fact.

II. ANALYSIS

A. Defendants' Motion to Exclude Expert Testimony of Dr. Robert Fincher (Doc. No. 105)

Dr. Fincher is Plaintiff's radiology/mammography expert. Plaintiff asked Dr. Fincher to review mammograms and determine whether "to a reasonable degree of medical probability, E+P had an effect on the density of Plaintiffs' breasts as measured by mammogram."[21] He also was asked to determine whether "based on the mammographic findings, E+P contributed to the development" of Plaintiff's breast cancer.[22]

Defendants contend that Dr. Fincher's opinions are not supported by reliable scientific evidence, are speculative, and are incomplete.[23]

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[18] Fed. R. Evid. 702(3).

[19] *Moore*, 151 F.3d at 275-76.

[20] *Id.* at 276.

[21] Doc. No. 177.

[22] *Id.*

[23] Doc. No. 106.

The motion is GRANTED in PART and DENIED in PART.

Dr. Fincher can testify generally about changes in breast density and the relationship, if any, between breast density and breast cancer risk. However, Dr. Fincher has not established, on this record, that changes in this Plaintiff's breast density, as related to HRT use, caused her cancer. Dr. Fincher's conclusions regarding any increase in Plaintiff's breast density after taking HRT lack reliability, because Dr. Fincher did not observe Plaintiff's pre-HRT mammograms. Even he concedes this point: "What I don't know is did it actually increase the degree of her breast density when she started taking the hormones, because there are no pre-hormone replacement therapy mammograms to compare."[24]

B. Defendants' Motion to Exclude Expert Testimony of Dr. Elizabeth Naftalis (Doc. No. 113)

Dr. Elizabeth Naftalis is Plaintiff's specific causation expert, who will testify that Plaintiff's ingestion of HRT was a substantial contributing factor in Plaintiff's development of hormone dependant breast cancer.[25]

Defendants assert that Dr. Naftalis's testimony should be excluded, because differential diagnosis is not a reliable method to determine the cause of Plaintiff's breast cancer, and Dr. Naftalis does not reliably apply her methodology to the facts of this case.[26]

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[24] Fincher Dep., July 20, 2007 Tr. at 41, lines 9-13.

[25] Doc. No. 183, Ex. 1.

[26] Doc. No. 114.

I believe that Judge Wilson's rulings in the previous bellwether trials are on point, and I adopt them here. To paraphrase: while the report is somewhat conclusive, rather than explanatory, I cannot say that Dr. Naftalis used improper methodology. She is qualified to testify that HRT more likely than not promoted Plaintiff's breast cancer. Her conclusions can be tested during cross-examination.[27]

Accordingly, Defendants' Motion to Exclude Expert Testimony of Dr. Elizabeth Naftalis (Doc. No. 113) is DENIED.

C. Defendants' Motion to Exclude Expert Testimony of Dr. Matthew Hollon (Doc. No. 109)

Dr. Hollon is Plaintiff's marketing expert. Plaintiff asserts that Dr. Hollon will testify regarding "pharmaceutical marketing and its impact on the medical community . . . ."[28] Plaintiff contends that Dr. Hollon will "educate the jury on marketing strategies, effectiveness and how Wyeth used the loopholes in the FDA regulations . . . to influence and persuade physicians about the safety and effectiveness of E+P drugs."[29]

1. Liability Stage

As mentioned in Section I of this Order, the testimony must be relevant, in that it must help the trier of fact either understand the evidence or determine a

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[27] See *In re Prempro, Reeves v. Wyeth*, No. 4:05-CV-00163, 2006 WL 2314062, at *3 (E.D. Ark. August 21, 2006) (citations omitted).

[28] Doc. No. 174.

[29] *Id.*

fact in issue.[30] The burden of establishing relevancy, reliability, and necessity of Dr. Hollon's testimony rests on Plaintiff.[31]

Here, Plaintiff asserts that if, during trial, Judge Wilson admits evidence that shows reliance on certain marketing materials, Dr. Hollon's testimony *may* become relevant. At this point, Plaintiff is unable to show whether Dr. Hollon's testimony is relevant or aids the trier of fact in understanding the evidence. Dr. Hollon appears to be qualified as an expert in pharmaceutical marketing, in general, but whether he can render an opinion on specific marketing is tied to what evidence is introduced at trial.

At this stage, Dr. Hollon must have examined the evidence necessary to form his expert opinion. Also, Plaintiff should be able to identify the marketing or promotional materials they believe would be admissible under Judge Wilson's previous rulings regarding reliance and marketing evidence. Instead, Plaintiff attempts to condition Dr. Hollon's opinions on evidence that *may* become available at trial.

Plaintiff concedes Dr. Hollon's opinions are based on what may become available during trial. Without the specific fact, data, or other evidence necessary for Dr. Hollon's opinion, I must GRANT Defendants' Motion to Exclude Expert Testimony of Dr. Matthew Hollon (Doc. No. 109), at this time.

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[30] *U.S. v. Cawthorn*, 429 F.3d at 799.

[31] *Moore v. Ashland Chem., Inc.*, 151 F.3d at 278-78.

2. Punitive Damages Stage

Judge Wilson previously addressed the issue of the admissibility of Dr. Hollon's testimony at the punitive damages stage, if there is one:

> It seems to me that any evidence of Defendant's "badness" during the punitive damage portion of the trial (if there is one) must be connected to Ms. Reeves's injury. However, the nexus between Plaintiff and the advertisements need not be as strong as the causation requirements during the liability stage of the trial. Dr. Hollon can testify regarding advertisements — however, those advertisements must pertain to issues that are directly linked to Plaintiff, e.g., cardiac benefit, breast cancer, etc. Dr. Hollon will not be permitted to testify regarding general badness or badness in the specific areas which are not connected to Ms. Reeves's injury.[32]

The Supreme Court held that:

> Evidence of actual harm to nonparties can help to show that the conduct that harmed the plaintiff also posed a substantial risk of harm to the general public, and so was particularly reprehensible-although counsel may argue in a particular case that conduct resulting in no harm to others nonetheless posed a grave risk to the public, or the converse. Yet for the reasons given above, a jury may not go further than this and use a punitive damages verdict to punish a defendant directly on account of harms it is alleged to have visited on nonparties.

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[32] *In re Prempro, Reeves v. Wyeth*, No. 4:05-CV-00163, 2006 WL 2314062, at *5 (E.D. Ark. August 21, 2006) (citations omitted).

Philip Morris U.S.A. v. Williams, 127 S. Ct. 1057, 1064 (2007).

Judge Wilson's ruling is still appropriate.

D. Dr. Austin Cellular Testimony

The November 9, 2007 Order noted that I could find nothing in the record regarding Dr. Austin's testimony on the development of breast cancer at the cellular level. Plaintiff supplemented the record on November 13, 2007. Based on this supplement, I am convinced that Dr. Austin can testify on this issue. The November 9, 2007 Order is VACATED to the extent that it granted Defendants' motion to exclude Dr. Austin's testimony regarding development of breast cancer at the cellular level. Accordingly, the motion is DENIED on this point.

IT IS SO ORDERED this 15th day of November, 2007.

APPENDIX F

UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

No. 03cv1507; No. 04 CV01163

IN RE: PREMPRO PRODUCTS LIABILITY LITIGATION.

LINDA REEVES, Plaintiff,

v.

WYETH, Defendant.

August 21, 2006

WILSON, United States District Judge.

ORDER

Pending are several *Daubert* motions: Defendant's Motion to Exclude Expert Testimony of Drs. Klimberg and Waldron as to Specific Causation (Doc. No. 74); Defendant's Motion to Exclude Expert Testimony of Dr. Hollon (Doc. No. 79); Defendant's Motion to Exclude Testimony of Dr. Gueriguian (Doc. No. 82); Defendant's Motion to Exclude Expert Testimony of Dr. Sackett (Doc. No. 85); and Defendant's Motion to Exclude

Expert Testimony of Dr. Austin (Doc. No. 91).[1] Also pending are Plaintiff's Motion to Preclude Defendant's Experts from Testifying That There is No Reliable Scientific Evidence that Combination Hormone Therapy Can Cause Breast Cancer (Doc. No. 131)[2] and Defendant's Motion for Summary Judgment Re: Specific Causation (Doc. No. 59).[3] Oral argument was heard on July 13-14, 2006 and again on July 31, 2006.

I. STANDARD

A. Burden of Proof

The admission of expert testimony is governed by Rule 702 of the Federal Rules of Evidence, which reads:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.[4]

When a party proffers an expert witness, deciding whether Rule 702 is satisfied is a preliminary issue

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[1] Plaintiff has responded to each motion (Doc. Nos. 142, 141, 148, 144, 136).

[2] Defendant has responded (Doc. No. 161).

[3] Plaintiff has responded (Doc. No. 111) and Defendant has replied (Doc. No. 120).

[4] Fed. R. Evid. 702.

governed by Federal Rule of Evidence 104(a).[5] Rule 104(a) requires the proponent of evidence to establish its admissibility by a preponderance of the evidence.[6] In determining admissibility, the court is not bound by any of the rules of evidence, except with regard to privilege.[7]

B. Legal Standard for Admissibility

The central inquiry under Rule 702 is whether the proffered expert's testimony is sufficiently reliable.[8] The trial court serves a gatekeeping function, ensuring that any expert testimony is reliable and relevant.[9]

To be admissible, expert testimony must satisfy the two prongs of Rule 702.[10] First, it must be based on scientific, technical, or other specialized knowledge.[11] If the testimony is scientific, it must be grounded in the methods and procedures of science.[12] Likewise, "knowledge" requires more than a subjective belief or an unsupported speculation, requiring instead an appropriate level of validation.[13] Second, the testimony must be relevant, in that it must help the trier of fact either understand the evidence or determine a fact in

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[5] *U.S. v. Martinez*, 3 F.3d 1191, 1196 n.10 (8th Cir. 1993).

[6] *Bourjaily v. U.S.*, 483 U.S. 171 (1987).

[7] Fed. R. Evid. 104(a).

[8] *First Nat'l Bank v. Benham*, 423 F.3d 855, 861 (8th Cir. 2005).

[9] *Id.*

[10] *U.S. v. Cawthorn*, 429 F.3d 793, 799 (8th Cir. 2005).

[11] *Id.*

[12] *Id.*

[13] *Id.* at 799-800 (quoting *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 590 (1993)).

issue.[14] The burden of establishing relevancy and reliability rests on the proponent of the expert testimony.[15]

Courts have used a variety of factors to determine the reliability of proffered expert testimony. The most frequently discussed factors are those derived from the Supreme Court's opinion in *Daubert*, where the Court established that the trial court may consider:

> (1) whether the theory or technique can be or has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether the theory or technique has a known or potential error rate and standards controlling the technique's operation; and (4) whether the theory or technique is generally accepted in the scientific community.[16]

Because the inquiry is "flexible and fact-specific, a court should use, adapt, or reject *Daubert* factors" as needed based on the facts of a particular case.[17]

The most recent amendments to Rule 702 added three general standards for courts to use in determining the reliability and relevance of proffered expert testimony. First, the proffered testimony must be based on sufficient facts or data.[18] Second, it must be the

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[14] *Id.* at 799.

[15] *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 278-78 (5th Cir. 1998).

[16] *Benham*, 423 F.3d at 861 (*citing Daubert*, 509 U.S. at 593-94).

[17] *Unrein v. Timesavers, Inc.*, 394 F.3d 1008, 1011 (8th Cir. 2005).

[18] Fed. R. Evid. 702(1).

product of reliable principles and methods.[19] Third, the expert must have applied those principles and methods reliably to the facts of the case.[20]

The focus is not on the expert's conclusion, but on the methodology.[21] The proponent of the testimony "need not prove . . . that the expert's testimony is correct, but . . . must prove by a preponderance of the evidence that the testimony is reliable."[22] Determining the validity of an expert's conclusions is the duty of the finder of fact.

II. ANALYSIS

A. Defendant's Motion to Exclude Expert Testimony of Drs. Klimberg and Waldron as to Specific Causation (Doc. No. 74)

Drs. Suzanne Klimberg and James A. Waldron were retained by Plaintiff to testify on both the general and specific causation of Plaintiff's breast cancer.

Defendant asserts several reasons for excluding the expert testimony of Drs. Klimberg and Waldron: (1) the opinions were created exclusively for this litigation; (2) the opinions are not based on sufficient facts or data;[23]

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[19] Fed. R. Evid. 702(2).

[20] Fed. R. Evid. 702(3).

[21] *Moore*, 151 F.3d at 275-76.

[22] *Id* at 276.

[23] Specifically Defendant claims that the opinions lack support because: (1) scientists do not know what causes breast cancer in an individual woman; (2) there is no test to identify the cause of breast cancer; (3) there is no physical characteristic that distinguishes breast cancers based on their cause; and (4) there is no way to separate the effect of naturally-occurring hormones and hormone therapy. *See* Doc. No. 76.

(3) differential diagnosis is not reliable to determine the cause of breast cancer; (4) and the "Gail Model" is not reliable to determine the cause of breast cancer.[24] Defendant also contends that Drs. Klimberg and Waldron are not qualified to testify because Dr. Klimberg has "never published — or even presented — the opinions regarding the cause of breast cancer" and Dr. Waldron's "previous experience with breast cancer was limited to analyzing breast biopsies and determining whether the tissue was cancerous, not identifying the cause of cancer."[25]

Plaintiff counters that Drs. Klimberg's and Waldron's opinions are based on scientifically reliable evidence. Additionally, Plaintiff claims that as a surgical oncologist and director of the breast cancer program at the Arkansas Cancer Research Center at UAMS[26] (Dr. Klimberg) and a diagnostic surgical pathologist and professor of pathology at UAMS (Dr. Waldron), both experts are qualified to testify as experts regarding causation.

Defendant's attacks on Drs. Klimberg's and Waldron's qualifications do not pass muster. Both experts have experience and understanding regarding breast cancer and their opinions are bottomed upon scientifically reliable information.

In formulating their opinions, Drs. Klimberg and Waldron relied on their training, knowledge, and experience as a surgical oncologist and pathologist, respectively. They reviewed and relied on numerous

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[24] Doc. No. 76.

[25] Doc. No. 76.

[26] University of Arkansas for Medical Sciences.

published, peer-reviewed medical literature and studies. While both reports are primarily conclusive, rather than explanatory, I don't believe that either expert used improper methodology. Dr. Klimberg's report on general causation reads:

> To make a causal assessment in an individual case, one would need to consider the totality of evidence, including statistical association, details about generally recognized and statistically significant risk factors, physiological response to the drugs, such as radiological evidence of changes in breast density before, during, and after hormone therapy use, pathological biomarkers in the breast tissue samples during biopsy and surgery, as well as duration of use of the hormone therapy drugs.[27]

Defendant faults the experts for using differential analysis. However, reliance on differential analysis is not fatal when epidemiological studies also support the expert's conclusions.[28] Raising significant questions about the experts' analysis and conclusions is something Defendant can do for the jury.

Also, Defendant claims that, since scientists don't know what causes breast cancer, Plaintiff's experts cannot opine that Plaintiff's breast cancer was caused by HRT. Defendant's focus is too narrow. Plaintiff's experts need not conclude that HRT definitively caused Plaintiff's cancer; they must only establish that it was

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[27] Doc. No. 109, Ex. 20.

[28] *See Ambrosini v. Labarraque*, 101 F.3d 129, 140-41 (D.C. Cir. 1996)(holding that expert testimony which relied, in part, on a differential analysis ruling out alternative sources of plaintiff's injury, was admissible, where epidemiological studies also indicated causal nexus).

more likely than not a cause — or that it promoted her cancer. That said, Plaintiff's experts' conclusions that HRT was "a substantial contributing factor"[29] in the development or promotion of Plaintiff's breast cancer chins the pole.

Again, while both reports are somewhat conclusive, rather than explanatory, I cannot say that either expert used improper methodology. In sum, both experts are qualified to testify that HRT more likely than not caused or promoted Plaintiff's breast cancer. Their conclusions can be tested during cross-examination.

B. Defendant's Motion to Exclude the Expert Testimony of Dr. Austin (Doc. No. 92)

Dr. Donald Austin will testify that, with proper monitoring, Wyeth could have and should have detected a signal in the 1980s that HRT may have been causing a disproportionate increase in certain types of breast cancer. Dr. Austin focused his report on "whether routine monitoring of breast cancer incidence from a publicly available source of such data of [sic] could have identified an anomalous increase in the incidence of invasive lobular carcinoma ["ILC"] in the U.S. during the period 1980-2000."[30]

Defendant contends that Dr. Austin's expert testimony should be excluded because: (1) it is unreliable since it was "developed solely for litigation," has not been tested, and has not been peer-reviewed or published;[31] (2) it does not "fit"[32] in the facts of this case

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[29] Doc. No. 109, Exs. 21, 29.

[30] Doc. No. 109, Ex. 1.

[31] Doc. No. 92.

because Ms. Reeves did not have ILC; (3) none of Dr. Austin's findings can be used as evidence that HRT increased the risk of breast cancer of any type; and (4) there is no evidence that information about increased risk of particular breast cancer cell types would have affected a physician's decisions to prescribe HRT.[32]

1. Unreliable — Wyeth's arguments on this point are standard *Daubert* challenges. However, these challenges are insufficient, even when considered cumulatively. First, "the fact of publication (or lack thereof) in a peer reviewed journal [is] . . . a relevant, though not dispositive, consideration."[34] Second, the fact that this research was conducted solely for this litigation, while noteworthy, is not fatal. When an expert develops opinions "expressly for the purposes of testifying," the proponent is required to "come forward with other objective, verifiable evidence that the testimony is based on 'scientifically valid principles.'"[35] Here, Dr. Austin's objective evidence is the SEER database he reviewed when compiling the data regarding the number of breast cancer incidences. As far as I can tell, Dr. Austin researched the database looking for a trend and reported the information that he discovered. Additionally, I don't find anything scientifically infirm about compiling data. It appears to me that the

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[32] *See Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1055 (8th Cir. 2000) (recognizing that "[i]n recent years the Supreme Court has put renewed emphasis on the importance of the 'fit' of an expert's opinion to the data or facts in the case").

[33] Doc. No. 92.

[34] *Daubert*, 509 U.S. at 593.

[35] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1317-18 (9th Cir. 1995) (quoting *Daubert*, 509 U.S. at 597).

conclusions he makes are based on a review of the objective evidence in the database.

2. **"Fit"** — Defendant also contends that Dr. Austin's findings are not relevant to this case because Plaintiff was diagnosed with ductal breast cancer, and Dr. Austin's findings refer to lobular breast cancer. Specifically, Dr. Austin concludes that his findings "represent a real and statistically significant increase in the proportions of ILC and Mixed Ductal/Lobular cancer relative to all invasive breast carcinoma."[36] Relying on Dr. Austin's report, Plaintiff contends that had Wyeth been keeping track of the information in the SEER database, it would have noticed "a surge in lobular breast cancer that mirrored the rise in the sale of E+P."[37] Plaintiff further contends that this "knowledge would have caused a reasonably prudent manufacturer to conduct further studies on all hormone positive breast cancers," probably resulting in the issuance of an adequate label before Plaintiff's ductal cancer was caused or promoted.[38]

While I have some doubt about Dr. Austin's analysis, "doubts regarding whether an expert's testimony will be useful should generally be resolved in favor of admissibility."[39]

3. **Causation** — Plaintiff and Dr. Austin both concede that he could not comment on causation.[40]

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[36] Doc. No. 109, Ex. 2.

[37] Doc. No. 266.

[38] *Id.*

[39] *Clark by and through Clark v. Heidrick*, 150 F.3d 912, 915 (8th Cir. 1998).

[40] Doc. No. 109, Ex. 1 and Doc. No. 285.

Accordingly, Dr. Austin will not be permitted to testify regarding causation.

4. Irrelevant to Prescribing Decision — Defendant also contends that Dr. Austin's testimony is irrelevant because "there is no evidence that information about risk of particular breast cancer cell types — as opposed to the overall risk of breast cancer — would matter to doctors in prescribing hormone therapy."[41] Since Plaintiff is presenting Dr. Austin's testimony to establish "what *defendants* should have done with the information, not what physicians would have done,"[42] Defendant is off the mark. Plaintiff's position is well-taken.

C. Defendant's Motion to Exclude the Expert Testimony of Dr. Hollon (Doc. No. 80)

Dr. Matthew Hollon plans to testify that Wyeth failed to meet the reasonable standard for care for drug promotion. He contends that Wyeth used promotional techniques irresponsibly and excessively, which directly influence physicians' prescribing practices.[43] Plaintiff asserts that Dr. Hollon should be permitted to testify that "Wyeth engaged in longstanding manipulation of conventional wisdom on hormone therapy . . . [and] that physicians are influenced by marketing, notwithstanding their denials."[44]

At the July 31, 2006 hearing, Plaintiff asserted that Dr. Hollon will testify in the punitive damages stage of trial only, should one become necessary. That being so,

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[41] Doc. No. 197.

[42] Doc. No. 136 (emphasis in original).

[43] Doc. No. 109, Ex. 16.

[44] Doc. No. 141.

Dr. Hollon's testimony will focus on what he believes Defendant did wrong with regards to marketing and he will link these actions to this case.[45]

Dr. Hollon is a practicing physician in internal medicine, with a Masters in Public Health, who has published several articles on pharmaceutical advertising.[46] He also teaches at the University of Washington in Seattle, and "has conducted independent social science research and written evidenced-based reviews and editorials" on pharmaceutical marketing.[47]

Defendant points out that although Dr. Hollon has published several pieces on pharmaceutical advertising, they were all editorials.[48] As stated above, Wyeth contends that Dr. Hollon should be prevented from testifying because his positions are not scientific, but personal opinions. Dr. Hollon's testimony need not be scientific. Rule 702 permits a witness to testify in the form of an opinion when that expert possesses scientific, technical, or other specialized knowledge that will assist the trier of fact. Clearly, Dr. Hollon has a knowledge of pharmaceutical marketing that is beyond a juror's common understanding. Although Defendant challenges the basis for his opinions, such challenges are issues for cross-examination.

However, Dr. Hollon's testimony about Wyeth's marketing will be limited to the issues in this case. For example, Plaintiff's position that "Dr. Hollon's expertise transcends the individual transaction to examine the

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[45] July 31, 2006, Tr. at 133.

[46] Doc. No. 109, Ex. 16.

[47] Doc. No. 141.

[48] July 31, 2006, Tr. at 141-142.

general influence of promotional activities that violate public health principles" and "that given the extent of the promotional campaign, [Wyeth] certainly had undue influence on prescribing practices within this country" is too broad. The United States Supreme Court has held that, even at the punitive damages stage of a trial, evidence of tortious conduct "must have a nexus to the specific harm suffered by the plaintiff . . . A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business."[49]

It seems to me that any evidence of Defendant's "badness" during the punitive damage portion of the trial (if there is one) must be connected to Ms. Reeves's injury. However, the nexus between Plaintiff and the advertisements need not be as strong as the causation requirements during the liability stage of the trial.[50] Dr. Hollon can testify regarding advertisements — however, those advertisements must pertain to issues that are directly linked to Plaintiff, e.g. cardiac benefit, breast cancer, etc. Dr. Hollon will not be permitted to testify regarding general badness or badness in the specific areas which is not connected to Ms. Reeves's injury.

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[49] *State Farm Mutual Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

[50] I previously held that Plaintiff would not be permitted to discuss advertisements that neither she nor her physician saw. However, at the punitive damages stage, the "nexus" can be a bit more attenuated.

D. Defendant's Motion to Exclude the Expert Testimony of Dr. John Gueriguian (Doc. No. 83).

In a July 24, 2006 letter, I requested that Plaintiff submit, as she suggested in the July 13-14, 2006 hearing, a short summary of Dr. Gueriguian's testimony.[51] In her July 27, 2006 response letter, Plaintiff asserted that Dr. Gueriguian would present testimony regarding: (1) the United States Food and Drug Administration's ("FDA") role and authority; (2) the use and purpose of labels/warnings in communicating risk information to physicians and patients; (3) the history of Wyeth's HRT drugs; (4) breast cancer signals and Wyeth's failure to test for a connection between breast cancer and HRT; (5) purported cardiac and cognitive benefits of HRT and Wyeth's failure to test for such benefits; (6) assessment of the risks and benefits of a prescription drug; and (7) the differences between "estrogen alone, Old E+P, and New Prempro."[52] In sum, Dr. Gueriguian will testify about the history of the development of HRT and that Wyeth had a duty to WHI-type randomized controlled trial in 1980s, because that is what a reasonably prudent pharmaceutical company would do.[53]

Wyeth contends that Dr. Gueriguian's testimony should be excluded because: (1) his opinions will not assist the jury; (2) he lacks expertise to testify about Wyeth's marketing practices or FDA's review of promotional pieces; (3) he knows nothing about this

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[51] Doc. No. 280.

[52] Doc. No. 289. *See also* Doc. No. 148.

[53] July 13, 2006, Tr. at 130.

specific case; and (4) he does not employ a reliable methodology.[54]

Dr. Gueriguian is a physician with specialty training in internal medicine, endocrinology, and pharmacology.[55] From 1978 to 1998 he worked at the FDA in the Division of Endocrine and Metabolic Drug Products. While at the FDA, Dr. Gueriguian reviewed drugs for safety and efficacy; applied FDA regulations regarding labeling, post-marketing surveillance, and approval of drugs; and was involved in the drafting of those regulations.[56]

1. FDA — Plaintiff's assertion that "Wyeth has specifically stated that it has no challenge to this testimony"[57] appears to be premature if I correctly read paragraph 1 of Defendant's response letter of July 28, 2006.[58] I hold, in general, that Dr. Gueriguian's testimony on the points in the letter regarding the FDA are admissible.[59] I reserve the right, of course, to exclude specific testimony at the trial. This means that Plaintiff must pare Dr. Gueriguian's testimony on this point, as well as others, to the essentials.

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[54] Doc. No. 83.

[55] Doc. No. 148.

[56] *Id.*

[57] Doc. No. 289.

[58] Doc. No. 297.

[59] *See In re Diet Drugs*, 2001 WL 454586, *24 (E.D. Pa. Feb. 1, 2001) (holding that "(a) Dr. Gueriguian's expert testimony about the standard of care in the pharmaceutical industry regarding the manner in which certain information should be communicated to the FDA; and (b) what FDA officials would have done with certain additional information such as particular adverse event reports" was admissible).

2. Label/Warnings — I will permit Dr. Gueriguian to relate a brief history (assuming it is based upon adequate data). Distilling voluminous documents is proper. While it is true that jurors can read documents, the trial would last months if they were required to read every admissible document. Further, I will permit Dr. Gueriguian to testify how he thinks Wyeth should have responded, but not how they would have.

3. History of Premarin and Prempro — a short history will be permitted. See the next preceding paragraph.

4. Breast Cancer Signals — Dr. Gueriguian will be permitted to testify that the recognition of signals should (not would) have led to studies and different warnings.

5. Cardiac Benefits — Ms. Reeves has testified or averred that she would not have taken the drug if she had known of the cardiac risks. It seems to me that this goes to causation or comparative fault.

6. Risk vs. Benefit — this will be permitted, in general. In other words, he can testify about the risk/benefit considerations with respect to prescription drugs in general as well as this particular drug.

7. "New Prempro" — After reading Plaintiff's Supplemental Filing Re: Wyeth's Motion in Limine No. 16 to Exclude Reference to "Low Dose" Prempro and considering argument heard during the August 15, 2006 hearing, I believe Dr. Gueriguian should be permitted to refer to "Low-Dose" Prempro. (Since the drafting of this order, Defendant has filed a knew motion regarding "Low-Dose" Prempro. This motion will be dealt with later today or tomorrow.)

Incidentally, I note that in paragraph 7 of Defendant's letter of July 28 (re: The Scope of Dr. Gueriguian's Testimony) states, "that is why this is a failure to warn, not a design defect case." I realize that this is Wyeth's position, but I have previously ruled that it is a design defect case too.

8. **Reasonable Drug Company** — The last paragraph of Defendant's letter refers to Dr. Gueriguian's proposed testimony about "a reasonable drug company." Arkansas Code Annotated § 16-116-104 provides:

> (a)(1) In determining the liability of the manufacturer, the state of scientific and technological knowledge available to the manufacturer or supplier at the time the product was placed on the market, rather than at the time of the injury, may be considered as evidence.
>
> (2) Consideration may also be given to the customary designs, methods, standards, and techniques of manufacturing, inspecting, and testing by other manufacturers or sellers of similar products.[60]

So, if Dr. Gueriguian has sufficient information, he can testify about the customs in the drug manufacturing world.

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[60] For a good summary of the law pertaining to "custom" *see* PROSSER AND KEETON ON THE LAW OF TORTS § 33 (5th Ed. 1984); *See also*, RESTATEMENT (THIRD) OF TORTS § 13 (2005).

E. Defendant's Motion to Exclude the Expert Testimony of Dr. David Sackett (Doc. No. 86)

Dr. Sackett is prepared to testify that (1) Wyeth violated the principles of evidence-based medicine by failing to conduct a WHI-type study in the 1970s, and (2) that Wyeth intended to promote HRT for its potential cardiac benefits. Plaintiff contends that Dr. Sackett's testimony supports her negligence claim.[61]

Defendant contends that Dr. Sackett's testimony regarding the duty to perform a large, randomized study will be duplicative of Dr. Gueriguian's testimony. Defendant asserts that Dr. Sackett can't say what kind of study Wyeth should have conducted, and he doesn't follow a methodology, rely on any regulatory requirements, nor does he rely on any industry standards.[62] Defendant also contends that Dr. Sackett's testimony doesn't "fit" with this case because it pertains to cardiac benefits and Plaintiff was prescribed HRT for osteoporosis.

Dr. Sackett is "a 40-year-veteran in the fields of internal medicine and clinical epidemiology, with particular interest in the principles and practices of evidence-based medicine."[63] He has also been the chair of several different randomized drug trials.[64] With these credentials, he is clearly qualified to testify about evidence-based medicine and the necessity of large

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[61] Doc. No. 144.

[62] July 14, 2006 Tr. at 169-70.

[63] Doc. No. 144.

[64] *Id.*

randomized clinical trials to determine the risks and benefits of drugs.

1. Duplicity — Defendant's position on duplicity is not convincing. First Dr. Sackett suggests the study should have been done in the 1970s and Dr. Gueriguian says it should have been done in the 1980s. Second, Plaintiff claims that although the testimony of Dr. Sackett and Dr. Gueriguian overlap, they both have their specialties and their opinions must be viewed together. Third, Plaintiff contends that she does not intend to ask them the same questions. If the testimony is too duplicative, I will intervene and encourage leaner presentations.

2. Type of Study — Contrary to Defendant's position that Dr. Sackett didn't explain what type of study should have been conducted, Dr. Sackett contends WHI-type study was necessary and would have put Defendant on notice regarding the alleged lack of cardiac benefits.[65] I agree with Defendant that Dr. Sackett's opinion regarding the specifics of the study is vague. However, it seems to me that Dr. Sackett's vagueness goes to the weight of his testimony rather than its admissibility.

3. "Fit" — Defendant's argument regarding "fit" lacks merit. There is a fact in dispute regarding whether Dr. Caldwell prescribed Plaintiff HRT for its alleged cardiac benefit. Also, apparently Plaintiff will testify that, if she had known of the cardiac risk, she would not have taken the drug. In light of that, I previously ruled that evidence regarding cardiac benefits is relevant to this case. Accordingly, Dr. Sackett's testimony regarding testing for a cardiac benefit is admissible.

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[65] *Id.*

Obviously, Dr. Sackett is not qualified to testify about FDA standards, but Plaintiff concedes that he's not going to talk about that. Nor will Dr. Sackett be permitted to testify as to what Wyeth should have or could have done to be a leader in the industry.

F. Plaintiff's Motion to Preclude Defendant's Experts from Testifying That There is No Reliable Scientific Evidence that Combination Hormone Therapy Can Cause Breast Cancer (Doc. No. 131).

As with Defendant's objections to Plaintiff's causation experts, each argument appears to go to credibility, not admissibility, and can be raised on cross-examination.

G. Defendant's Motion for Summary Judgment Re: Specific Causation (Doc. No. 59)

Since Defendant's Motion to Exclude Expert Testimony of Drs. Klimberg and Waldron as to Specific Causation was denied, material facts remain in dispute as to causation.

CONCLUSION

Based on the findings of fact and conclusions of law made during the hearings and above:

1. Defendant's Motion to Exclude Expert Testimony of Drs. Klimberg and Waldron as to Specific Causation (Doc. No. 74) is DENIED.

2. Defendant's Motion to Exclude Expert Testimony of Dr. Hollon (Doc. No. 79) is DENIED, except as to the limitations mentioned above.

3. Defendant's Motion to Exclude Testimony of Dr. Gueriguian (Doc. No. 82) is DENIED, except as to the limitations mentioned above.

4. Defendant's Motion to Exclude Expert Testimony of Dr. Sackett (Doc. No. 85) is GRANTED regarding testimony about FDA standards and what Defendant could do to be a leader in the industry. The motion is DENIED regarding the remaining points.

5. Defendant's Motion to Exclude Expert Testimony of Dr. Austin (Doc. No. 91) is GRANTED as it concerns testimony regarding causation and DENIED as to the remaining points.

6. Plaintiff's Motion to Preclude Defendant's Experts from Testifying That There is No Reliable Scientific Evidence that Combination Hormone Therapy Can Cause Breast Cancer (Doc. No. 131) is DENIED.

7. Defendant's Motion for Summary Judgment Re: Specific Causation (Doc. No. 59) is DENIED.

IT IS SO ORDERED this 21st day of August, 2006.